SA 4299 proposed by Mr. REID (for Mr. DORGAN (for himself, Mr. WELLSTONE, Mr. JEFFORDS, Ms. STABENOW, Ms. COLLINS, Mr. LEVIN, Mr. JOHNSON, Mr. MILLER, Mr. DURBIN, Mr. FEINGOLD, and Mr. HARKIN)) to the bill (S. 812) to amend the Federal Food, Drug, and Cosmetic Act to provide greater access to affordable pharmaceuticals; which was ordered to lie on the table.

TEXT OF AMENDMENTS

SA 4327. Mr. WELLSTONE submitted an amendment intended to be proposed by him to the bill S. 812, to amend the Federal Food, Drug, and Cosmetic Act to provide greater access to affordable pharmaceuticals; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

SEC. ___. STATE PRESCRIPTION DRUG DISCOUNT.

(a) FINDINGS.—Congress makes the following findings:

(1) More than 70,000,000 Americans, including more than 18,000,000 Medicare beneficiaries, are uninsured or underinsured for prescription drug coverage.

(2) High prescription drug prices are denying uninsured and underinsured Americans access to medically necessary care, thereby threatening their health and safety. Many of these Americans require repeated doctor or medical clinic appointments, becoming sicker because they cannot afford to take the drugs prescribed for them. Many are admitted to or treated at hospitals because they cannot afford the drugs prescribed for them that could have prevented the need for hospitalization. Many enter expensive institutional care settings because they cannot afford the prescription drugs that could have supported them outside of an institution. In each of these circumstances, uninsured and underinsured residents too often become medicaid recipients because of their inability to afford prescription drugs.

(3) Pursuant to the Social Security Act, State medicaid programs receive discounts in the form of rebates for outpatient prescription drugs. On average, these rebates provide discounts of more than 40 percent off retail prices.

(4) In 49 States, individual Americans do not have access to medicaid rebates. But in 1 State, since June 1, 2001, over 100,000 Americans have received discounts from those rebates through the ''Healthy Maine'' program. This program, established as a demonstration project pursuant to a waiver from the Secretary of Health and Human Services has proven to work. Americans need that program replicated in every State, immediately.

(5) The Federal and State governments are the only agents that, as a practical matter, can play an effective role as a market participant on behalf of Americans who are uninsured or underinsured.

(b) STATE PRESCRIPTION DISCOUNT PROGRAM.—

(1) IN GENERAL.—Section 1927(a) of the Social Security Act (42 U.S.C. 1396r–8(a)) is amended by adding at the end the following:

''(7) REQUIREMENTS RELATING TO AGREEMENTS FOR DRUGS PROCURED BY INDIVIDUALS THROUGH STATE PRESCRIPTION DRUG DISCOUNT PROGRAMS.—

''(A) IN GENERAL.—A manufacturer meets the requirements of this paragraph if the manufacturer enters into an agreement with the State to make rebate payments for drugs covered by a State prescription drug discount program in the same amounts as are paid by the manufacturer to the State for such drugs under a rebate agreement described in subsection (b).

''(B) STATE PRESCRIPTION DRUG DISCOUNT PROGRAM DEFINED.—

''(i) IN GENERAL.—In this paragraph, the term 'State prescription drug discount program' means a State program under which, with respect to a rebate period, not less than the amount equal to 95 percent of all the rebates paid to the State under agreements entered into under subparagraph (A) during such period is provided to eligible State residents in the form of discounted prices for the purchase of outpatient prescription drugs.

''(ii) ELIGIBLE STATE RESIDENT.—For purposes of clause (i), the term 'eligible State resident' means an individual who is a State resident and—

''(I) who is eligible for benefits under title XVIII; or

''(II) whose income does not exceed 300 percent of the income official poverty line (as defined by the Office of Management and Budget, and revised annually in accordance with section 673(2) of the Omnibus Budget Reconciliation Act of 1981) applicable to a family of the size involved.

''(iii) ADDITIONAL SUBSIDIES.—Nothing in this subparagraph shall be construed as—

''(I) requiring a State to expend State funds to carry out a State prescription drug discount program; or

''(II) prohibiting a State from electing to contribute State funds to a State prescription drug discount program to provide greater subsidies to eligible State residents for outpatient prescription drugs covered under the program.

''(C) NO OFFSET AGAINST MEDICAL ASSISTANCE.—Amounts received by a State under an agreement entered into under subparagraph (A) in any quarter shall not be considered to be a reduction in the amount expended under the State plan in the quarter for medical assistance for purposes of section 1903(a)(1).''.

(2) CONFORMING AMENDMENT.—The first sentence of section 1927(a)(1) of the Social Security Act (42 U.S.C. 1396r–8(a)(1)) is amended, by striking ''and paragraph (6)'' and inserting '', paragraph (6), and paragraph (7)''.

(c) ENHANCED REBATES FOR STATE MEDICAID PROGRAMS.—Section 1927(b)(1)(B) of the Social Security Act (42 U.S.C. 1396r–8(b)(1)(B) is amended—

(1) by striking ''Amounts'' and inserting the following:

''(i) IN GENERAL.—Except as provided in clause (ii) and subsection (a)(7)(C), amounts''; and

(2) by adding at the end the following:

''(ii) ENHANCED REBATE.—In the case of a State that has a State prescription drug discount program described in subsection (a)(7) and that has entered into a rebate agreement described in paragraph (1) or (4) of subsection (a) that provides a greater rebate for a covered outpatient drug than the rebate that would be paid for the covered outpatient drug under subsection (c), then, notwithstanding clause (i), only the amount equal to ½ of the difference between the amount received by the State in any quarter under such a rebate agreement and the amount of the rebate that would be paid under subsection (c) for such covered outpatient drug shall be considered to be a reduction in the amount expended under the State plan in the quarter for medical assistance for purposes of section 1903(a)(1).''.

(d) EFFECTIVE DATE.—The amendments made by this section take effect on January 1, 2004.

SA 4328. Mr. BINGAMAN submitted an amendment intended to be proposed by him to the bill S. 812, to amend the Federal Food, Drug, and Cosmetic Act to provide greater access to affordable pharmaceuticals; which was ordered to lie on the table; as follows:

At the end, add the following:

SEC. ___. CLARIFICATION OF INCLUSION OF INPATIENT DRUG PRICES CHARGED TO CERTAIN PUBLIC HOSPITALS IN THE BEST PRICE EXEMPTIONS ESTABLISHED FOR PURPOSES OF THE MEDICAID DRUG REBATE PROGRAM.

Section 1927(c)(1)(C)(ii) of the Social Security Act (42 U.S.C. 1396r–8(c)(1)(C)(ii)) is amended—

(1) in subclause (II), by striking ''and'' at the end;

(2) in subclause (Ill), by striking the period and inserting ''; and''; and

(3) by adding at the end the following:

''(IV) with respect to a covered entity described in section 340B(a)(4)(L) of the Public Health Service Act, shall, in addition to any prices excluded under clause (i)(I), exclude any price charged on or after the date of enactment of this subparagraph, for any drug, biological product, or insulin provided as part of, or as incident to and in the same setting as, inpatient hospital services (and for which payment may be made under this title as part of payment for and not as direct reimbursement for the drug).''.

SA 4329. Mr. DURBIN (for himself, Mr. DEWINE, Mr. DORGAN, Mr. LEVIN, and Mr. JOHNSON) submitted an amendment intended to be proposed by him to the bill S. 812, to amend the Federal Food, Drug, and Cosmetic Act to provide greater access to affordable pharmaceuticals; which was ordered to lie on the table; as follows:

At the end, add the following:

SEC. ___. COMPREHENSIVE COVERAGE OF IMMUNOSUPPRESSIVE DRUGS UNDER THE MEDICARE PROGRAM.

(a) IN GENERAL.—Section 1861(s)(2)(J) of the Social Security Act (42 U.S.C. 1395x(s)(2)(J)), as amended by section 113(a) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (114 Stat. 2763A–473), as enacted into law by section 1(a)(6) of Public Law 106–554, is amended by striking '', to an individual who receives'' and all that follows before the semicolon at the end and inserting ''to an individual who has received an organ transplant''.

(b) EFFECTIVE DATE.—The amendments made by this section shall apply to drugs furnished on or after the date of enactment of this Act.

SEC. ___. PROVISION OF APPROPRIATE COVERAGE OF IMMUNOSUPPRESSIVE DRUGS UNDER THE MEDICARE PROGRAM FOR ORGAN TRANSPLANT RECIPIENTS.

(a) CONTINUED ENTITLEMENT TO IMMUNOSUPPRESSIVE DRUGS.—

(1) KIDNEY TRANSPLANT RECIPIENTS.—Section 226A(b)(2) of the Social Security Act (42 U.S.C. 426–1(b)(2)) is amended by inserting ''(except for coverage of immunosuppressive drugs under section 1861(s)(2)(J))'' after ''shall end''.

(2) OTHER TRANSPLANT RECIPIENTS.—The flush matter following paragraph (2)(C)(ii)(II) of section 226(b) of the Social Security Act (42 U.S.C. 426(b)) is amended by striking ''of this subsection)'' and inserting ''of this subsection and except for coverage of immunosuppressive drugs under section 1861(s)(2)(J))''.

(3) APPLICATION.—Section 1836 of the Social Security Act (42 U.S.C. 1395o) is amended—

(A) by striking ''Every individual who'' and inserting ''(a) IN GENERAL.—Every individual who''; and

(B) by adding at the end the following new subsection:

''(b) SPECIAL RULES APPLICABLE TO INDIVIDUALS ONLY ELIGIBLE FOR COVERAGE OF IMMUNOSUPPRESSIVE DRUGS.—

''(1) IN GENERAL.—In the case of an individual whose eligibility for benefits under this title has ended except for the coverage of immunosuppressive drugs by reason of section 226(b) or 226A(b)(2), the following rules shall apply:

''(A) The individual shall be deemed to be enrolled under this part for purposes of receiving coverage of such drugs.

''(B) The individual shall be responsible for the full amount of the premium under section 1839 in order to receive such coverage.

''(C) The provision of such drugs shall be subject to the application of—

''(i) the deductible under section 1833(b); and

''(ii) the coinsurance amount applicable for such drugs (as determined under this part).

''(D) If the individual is an inpatient of a hospital or other entity, the individual is entitled to receive coverage of such drugs under this part.

''(2) ESTABLISHMENT OF PROCEDURES IN ORDER TO IMPLEMENT COVERAGE.—The Secretary shall establish procedures for—

''(A) identifying beneficiaries that are entitled to coverage of immunosuppressive drugs by reason of section 226(b) or 226A(b)(2); and

''(B) distinguishing such beneficiaries from beneficiaries that are enrolled under this part for the complete package of benefits under this part.''.

(4) TECHNICAL AMENDMENT.—Subsection (c) of section 226A of the Social Security Act (42 U.S.C. 426–1), as added by section 201(a)(3)(D)(ii) of the Social Security Independence and Program Improvements Act of 1994 (Public Law 103–296; 108 Stat. 1497), is redesignated as subsection (d).

(b) EXTENSION OF SECONDARY PAYER REQUIREMENTS FOR ESRD BENEFICIARIES.—Section 1862(b)(1)(C) of the Social Security Act (42 U.S.C. 1395y(b)(1)(C)) is amended by adding at the end the following new sentence: ''With regard to immunosuppressive drugs furnished on or after the date of enactment of this sentence, this subparagraph shall be applied without regard to any time limitation.''.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to drugs furnished on or after the date of enactment of this Act.

SEC. ___. PLANS REQUIRED TO MAINTAIN COVERAGE OF IMMUNOSUPPRESSIVE DRUGS.

(a) APPLICATION TO CERTAIN HEALTH INSURANCE COVERAGE.—

(1) IN GENERAL.—Subpart 2 of part A of title XXVII of the Public Health Service Act (42 U.S.C. 300gg–4 et seq.) is amended by adding at the end the following:

''SEC. 2707. COVERAGE OF IMMUNOSUPPRESSIVE DRUGS.

''A group health plan (and a health insurance issuer offering health insurance coverage in connection with a group health plan) shall provide coverage of immunosuppressive drugs that is at least as comprehensive as the coverage provided by such plan or issuer on the day before the date of enactment of this section, and such requirement shall be deemed to be incorporated into this section.''.

(2) CONFORMING AMENDMENT.—Section 2721(b)(2)(A) of the Public Health Service Act (42 U.S.C. 300gg–21(b)(2)(A)) is amended by inserting ''(other than section 2707)'' after ''requirements of such subparts''.

(b) APPLICATION TO GROUP HEALTH PLANS AND GROUP HEALTH INSURANCE COVERAGE UNDER THE EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974.—

(1) IN GENERAL.—Subpart B of part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1185 et seq.) is amended by adding at the end the following new section:

''SEC. 714. COVERAGE OF IMMUNOSUPPRESSIVE DRUGS.

''A group health plan (and a health insurance issuer offering health insurance coverage in connection with a group health plan) shall provide coverage of immunosuppressive drugs that is at least as comprehensive as the coverage provided by such plan or issuer on the day before the date of enactment of this sentence, and such requirement shall be deemed to be incorporated into this section.''.

(2) CONFORMING AMENDMENTS.—

(A) Section 732(a) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1185(a)) is amended by striking ''section 711'' and inserting ''sections 711 and 714''.

(B) The table of contents in section 1 of the Employee Retirement Income Security Act of 1974 is amended by inserting after the item relating to section 713 the following new item:

''Sec. 714. Coverage of immunosuppressive drugs.''.

(c) APPLICATION TO GROUP HEALTH PLANS UNDER THE INTERNAL REVENUE CODE OF 1986.—Subchapter B of chapter 100 of the Internal Revenue Code of 1986 is amended—

(1) in the table of sections, by inserting after the item relating to section 9812 the following new item:

''Sec. 9813. Coverage of immunosuppressive drugs.'';

and

(2) by inserting after section 9812 the following:

''SEC. 9813. COVERAGE OF IMMUNOSUPPRESSIVE DRUGS.

''A group health plan shall provide coverage of immunosuppressive drugs that is at least as comprehensive as the coverage provided by such plan on the day before the date of enactment of this sentence, and such requirement shall be deemed to be incorporated into this section.''.

(d) EFFECTIVE DATE.—The amendments made by this section shall apply to plan years beginning on or after January 1, 2003.

SA 4330. Mr. ENZI submitted an amendment intended to be proposed by him to the bill S. 812, to amend the Federal Food, Drug, and Cosmetic Act to provide greater access to affordable pharmaceuticals; which was ordered to lie on the table; as follows:

Beginning on page 27, strike line 15 and all that follows through page 28, line 18 and insert the following:

''(E) NO CLAIM FOR PATENT INFRINGEMENT.—An owner of a patent with respect to''.

SA 4331. Mr. ENZI submitted an amendment intended to be proposed by him to the bill S. 812, to amend the Federal Food, Drug, and Cosmetic Act to provide greater access to affordable pharmaceuticals; which was ordered to lie on the table; as follows:

Beginning on page 27, strike line 15 and all that follows through page 28, line 16, and insert the following:

''(E) CORRECTION OR DELETION OF PATENT INFORMATION.—

''(i) IN GENERAL.—A person that has filed an application under subsection (b)(2) or (j) for a drug may submit to arbitration a claim to require the holder of the application to amend the application—

''(I) to correct patent information filed under subparagraph (A); or

''(II) to delete the patent information in its entirety for the reason that—

''(aa) the patent does not claim the drug for which the application was approved; or

''(bb) the patent does not claim an approved method of using the drug.

''(ii) AMERICAN ARBITRATION ASSOCIATION.—Arbitration under clause (i) shall be administered by the American Arbitration Association, in accordance with the Commercial Arbitration Rules.

''(iii) DECISION.—

''(I) TIMING.—Not later than 180 days after the date on which an arbitrator receives a written request for arbitration under this subparagraph, the arbitrator shall render a decision with respect to the claim.

''(II) LIMITATION.—In rendering a decision under subclause (I), the arbitrator shall not—

''(aa) order the correction of patent information filed under subparagraph (B); or

''(bb) award monetary damages.

''(III) BINDING EFFECT.—A decision rendered under subclause (I)—

''(aa) shall be final and binding; and

''(bb) may be entered in any court having jurisdiction over the claim.

SA 4332. Mr. ENZI submitted an amendment intended to be proposed by him to the bill S. 812, to amend the Federal Food, Drug, and Cosmetic Act to provide greater access to affordable pharmaceuticals; which was ordered to lie on the table; as follows:

Beginning on page 28, strike line 17 and all that follows through page 39, line 18, and insert the following:

(2) TRANSITION PROVISION.—Each holder of an application for approval of a new drug under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) that has been approved before the date of enactment of this Act shall amend the application to include the patent information required under the amendment made by paragraph (1) not later than the date that is 30 days after the date of enactment of this Act (unless the Secretary of Health and Human Services extends the date because of extraordinary or unusual circumstances).

(b) FILING WITH AN APPLICATION.—Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended—

(1) in subsection (b)(2)—

(A) in subparagraph (A), by striking ''and'' at the end;

(B) in subparagraph (B), by striking the period at the end and inserting ''; and''; and

(C) by adding at the end the following:

''(C) with respect to a patent that claims both the drug and a method of using the drug or claims more than 1 method of using the drug for which the application is filed—

''(i) a certification under subparagraph (A)(iv) on a claim-by-claim basis; and

''(ii) a statement under subparagraph (B) regarding the method of use claim.''; and

(2) in subsection (j)(2)(A), by inserting after clause (viii) the following:

''With respect to a patent that claims both the drug and a method of using the drug or claims more than 1 method of using the drug for which the application is filed, the application shall contain a certification under clause (vii)(IV) on a claim-by-claim basis and a statement under clause (viii) regarding the method of use claim.''.

SEC. 4. LIMITATION OF 30-MONTH STAY TO CERTAIN PATENTS.

(a) ABBREVIATED NEW DRUG APPLICATIONS.—Section 505(j)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)) is amended—

(1) in subparagraph (B)—

(A) in clause (iii)—

(i) by striking ''(iii) If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii),'' and inserting the following:

''(iii) SUBCLAUSE (IV) CERTIFICATION WITH RESPECT TO CERTAIN PATENTS.—If the applicant made a certification described in paragraph (2)(A)(vii)(IV) with respect to a patent (other than a patent that claims a process for manufacturing the listed drug) for which patent information was filed with the Secretary under subsection (c)(2)(A),''; and

(ii) by adding at the end the following: ''The 30-month period provided under the second sentence of this clause shall not apply to a certification under paragraph (2)(A)(vii)(IV) made with respect to a patent for which patent information was filed with the Secretary under subsection (c)(2)(B).'';

(B) by redesignating clause (iv) as clause (v); and

(C) by inserting after clause (iii) the following:

''(iv) SUBCLAUSE (IV) CERTIFICATION WITH RESPECT TO OTHER PATENTS.—

''(I) IN GENERAL.—If the applicant made a certification described in paragraph (2)(A)(vii)(IV) with respect to a patent not described in clause (iii) for which patent information was published by the Secretary under subsection (c)(2)(D), the approval shall be made effective on the date that is 45 days after the date on which the notice provided under paragraph (2)(B) was received, unless a civil action for infringement of the patent, accompanied by a motion for preliminary injunction to enjoin the applicant from engaging in the commercial manufacture or sale of the drug, was filed on or before the date that is 45 days after the date on which the notice was received, in which case the approval shall be made effective—

''(aa) on the date of a court action declining to grant a preliminary injunction; or

''(bb) if the court has granted a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug—

''(AA) on issuance by a court of a determination that the patent is invalid or is not infringed;

''(BB) on issuance by a court of an order revoking the preliminary injunction or permitting the applicant to engage in the commercial manufacture or sale of the drug; or

''(CC) on the date specified in a court order under section 271(e)(4)(A) of title 35, United States Code, if the court determines that the patent is infringed.

''(II) COOPERATION.—Each of the parties shall reasonably cooperate in expediting a civil action under subclause (I).

''(III) EXPEDITED NOTIFICATION.—If the notice under paragraph (2)(B) contains an address for the receipt of expedited notification of a civil action under subclause (I), the plaintiff shall, on the date on which the complaint is filed, simultaneously cause a notification of the civil action to be delivered to that address by the next business day.''; and

(2) by inserting after subparagraph (B) the following:

''(C) FAILURE TO BRING INFRINGEMENT ACTION.—If, in connection with an application under this subsection, the applicant provides an owner of a patent notice under paragraph (2)(B) with respect to the patent, and the owner of the patent fails to bring a civil action against the applicant for infringement of the patent on or before the date that is 45 days after the date on which the notice is received, the owner of the patent shall be barred from bringing a civil action for infringement of the patent against the applicant with respect to the application.''.

(b) OTHER APPLICATIONS.—Section 505(c)) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)) (as amended by section 9(a)(3)(A)(iii)) is amended—

(1) in paragraph (3)—

(A) in subparagraph (C)—

(i) by striking ''(C) If the applicant made a certification described in clause (iv) of subsection (b)(2)(A),'' and inserting the following:

''(C) CLAUSE (iv) CERTIFICATION WITH RESPECT TO CERTAIN PATENTS.—If the applicant made a certification described in subsection (b)(2)(A)(iv) with respect to a patent (other than a patent that claims a process for manufacturing the listed drug) for which patent information was filed with the Secretary under paragraph (2)(A),''; and

(ii) by adding at the end the following: ''The 30-month period provided under the second sentence of this subparagraph shall not apply to a certification under subsection (b)(2)(A)(iv) made with respect to a patent for which patent information was filed with the Secretary under paragraph (2)(B).''; and

(B) by inserting after subparagraph (C) the following:

''(D) CLAUSE (iv) CERTIFICATION WITH RESPECT TO OTHER PATENTS.—

''(i) IN GENERAL.—If the applicant made a certification described in subsection (b)(2)(A)(iv) with respect to a patent not described in subparagraph (C) for which patent information was published by the Secretary under paragraph (2)(D), the approval shall be made effective on the date that is 45 days after the date on which the notice provided under subsection (b)(3) was received, unless a civil action for infringement of the patent, accompanied by a motion for preliminary injunction to enjoin the applicant from engaging in the commercial manufacture or sale of the drug, was filed on or before the date that is 45 days after the date on which the notice was received, in which case the approval shall be made effective—

''(I) on the date of a court action declining to grant a preliminary injunction; or

''(II) if the court has granted a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug—

''(aa) on issuance by a court of a determination that the patent is invalid or is not infringed;

''(bb) on issuance by a court of an order revoking the preliminary injunction or permitting the applicant to engage in the commercial manufacture or sale of the drug; or

''(cc) on the date specified in a court order under section 271(e)(4)(A) of title 35, United States Code, if the court determines that the patent is infringed.

''(ii) COOPERATION.—Each of the parties shall reasonably cooperate in expediting a civil action under clause (i).

''(iii) EXPEDITED NOTIFICATION.—If the notice under subsection (b)(3) contains an address for the receipt of expedited notification of a civil action under clause (i), the plaintiff shall, on the date on which the complaint is filed, simultaneously cause a notification of the civil action to be delivered to that address by the next business day.''; and

(2) by inserting after paragraph (3) the following:

''(4) FAILURE TO BRING INFRINGEMENT ACTION.—If, in connection with an application under subsection (b)(2), the applicant provides an owner of a patent notice under subsection (b)(3) with respect to the patent, and the owner of the patent fails to bring a civil action against the applicant for infringement of the patent on or before the date that is 45 days after the date on which the notice is received, the owner of the patent shall be barred from bringing a civil action for infringement of the patent against the applicant with respect to the application.''.

SA 4333. Mr. ENZI submitted an amendment intended to be proposed by him to the bill S. 812, to amend the Federal Food, Drug, and Cosmetic Act to provide greater access to affordable pharmaceuticals; which was ordered to lie on the table; as follows:

Beginning on page 31, strike line 12 and all that follows through page 40 and insert the following:

SEC. 4. 30-MONTH STAY.

(a) ABBREVIATED NEW DRUG APPLICATIONS.—Section 505(j)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)) is amended—

(1) in subparagraph (B)(iii)—

(A) by striking ''(iii) If the applicant'' and inserting the following:

''(iii) SUBCLAUSE (IV) CERTIFICATION.—If the applicant''; and

(B) by adding at the end the following: ''The 30-month period provided under this clause shall not apply to a certification under paragraph (2)(A)(vii)(IV) made with respect to a patent for which patent information was filed with the Secretary after the filing of the application under this subsection that contains the certification.''; and

(2) by inserting after subparagraph (B) the following:

''(C) FAILURE TO BRING INFRINGEMENT ACTION.—If, in connection with an application under this subsection, the applicant provides an owner of a patent notice under paragraph (2)(B) with respect to the patent, and the owner of the patent fails to bring a civil action against the applicant for infringement of the patent on or before the date that is 45 days after the date on which the notice is received, the owner of the patent shall be barred from bringing a civil action for infringement of the patent in connection with the development, manufacture, use, offer to sell, or sale of the drug for which the application was filed or approved under this subsection.''.

(b) OTHER APPLICATIONS.—Section 505(c)) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)) is amended—

(1) in paragraph (3)(C)—

(A) by striking ''(C) If the applicant'' and inserting the following:

''(C) CLAUSE (iv) CERTIFICATION.—If the applicant''; and

(B) by adding at the end the following: ''The 30-month period provided under this subparagraph shall not apply to a certification under subsection (b)(2)(A)(iv) made with respect to a patent for which patent information was filed with the Secretary after the filing of the application described in subsection (b)(2) that contains the certification.''; and

(2) by inserting after paragraph (3) the following:

''(4) FAILURE TO BRING INFRINGEMENT ACTION.—If, in connection with an application under subsection (b)(2), the applicant provides an owner of a patent notice under subsection (b)(3) with respect to the patent, and the owner of the patent fails to bring a civil action against the applicant for infringement of the patent on or before the date that is 45 days after the date on which the notice is received, the owner of the patent shall be barred from bringing a civil action for infringement of the patent in connection with the development, manufacture, use, offer to sell, or sale of the drug for which the application was filed or approved under subsection (b)(2).''.

SA 4334. Mr. NICKLES submitted an amendment intended to be proposed by

him to the bill S. 812, to amend the Federal Food, Drug, and Cosmetic Act to provide greater access to affordable pharmaceuticals; which was ordered to lie on the table; as follows:

At the appropriate place, add the following:

SEC. ___. NONAPPLICATION OF STATE AUTHORITY TO ENTER INTO DRUG REBATE AGREEMENTS IF THE AGREEMENTS WOULD RESULT IN INCREASED MEDICAID DRUG COSTS.

Notwithstanding any other provision of this Act, section 1927 of the Social Security Act (42 U.S.C. 1396r–8) shall be applied without regard to subsection (l) (as added by this Act) if the Secretary of Health and Human Services determines that the application of that subsection would result in an increase in expenditures under the medicaid program established under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) for covered outpatient drugs (as defined in section 1927(k)(2) of that Act (42 U.S.C. 1396r–8(k)(2)).

SA 4335. Mr. NICKLES submitted an amendment intended to be proposed to amendment SA 4299 proposed by Mr. REID (for Mr. DORGAN (for himself, Mr. WELLSTONE, Mr. JEFFORDS, Ms. STABENOW, Ms. COLLINS, Mr. LEVIN, Mr. JOHNSTON, Mr. MILLER, Mr. DURBIN, Mr. FEINGOLD, and Mr. HARKIN)) to the bill (S. 812) to amend the Federal Food, Drug, and Cosmetic Act to provide greater access to affordable pharmaceuticals; which was ordered to lie on the table; as follows:

At the appropriate place, add the following:

SEC. ___. NONAPPLICATION OF STATE AUTHORITY TO ENTER INTO DRUG REBATE AGREEMENTS IF THE AGREEMENTS WOULD RESULT IN INCREASED MEDICAID DRUG COSTS.

Notwithstanding any other provision of this Act, section 1927 of the Social Security Act (42 U.S.C. 1396r–8) shall be applied without regard to subsection (l) (as added by this Act) if the Secretary of Health and Human Services determines that the application of that subsection would result in an increase in expenditures under the medicaid program established under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) for covered outpatient drugs (as defined in section 1927(k)(2) of that Act (42 U.S.C. 1396r–8(k)(2)).

SA 4336. Mr. NICKLES submitted an amendment intended to be proposed by him to the bill S. 812, to amend the Federal Food, Drug, and Cosmetic Act to provide greater access to affordable pharmaceuticals; which was ordered to lie on the table; as follows:

At the appropriate place, add the following:

SEC. ___. SCOPE OF APPLICATION OF TEMPORARY INCREASE IN FMAP.

Section ___(a)(5) of this Act (relating to the scope of application of the temporary increase in the State Federal medical assistance percentage) is amended—

(1) by striking the period at the end of subparagraph (B) and inserting ''; or''; and

(2) by adding at the end the following:

''(C) payments that are in excess of the aggregate upper payment limits applicable to the medicaid program, as determined under part 447 of title 42 of the Code of Federal Regulations, (or that would be considered to be in excess of such limits if a transition period described in section 447.272(e) or 447.321(e) of title 42 of the Code of Federal Regulations) did not apply to the payments).''.

SA 4337. Mr. NICKLES submitted an amendment intended to be proposed to amendment SA 4299 proposed by Mr. REID (for Mr. DORGAN (for himself, Mr. WELLSTONE, Mr. JEFFORDS, Ms. STABENOW, Ms. COLLINS, Mr. LEVIN, Mr. JOHNSON, Mr. MILLER, Mr. DURBIN, Mr. FEINGOLD, and Mr. HARKIN)) to the bill (S. 812) to amend the Federal Food, Drug, and Cosmetic Act to provide greater access to affordable pharmaceuticals; which was ordered to lie on the table; as follows:

At the appropriate place, add the following:

''(C) payments that are in excess of the aggregate upper payment limits applicable to the medicaid program, as determined under part 447 of title 42 of the Code of Federal Regulations, (or that would be considered to be in excess of such limits if a transition period described in section 447.272(e) or 447.321(e) of title 42 of the Code of Federal Regulations) did not apply to the payments).''.

SA 4338. Mr. NICKLES submitted an amendment intended to be proposed by him to the bill S. 812, to amend the Federal Food, Drug, and Cosmetic Act to provide greater access to affordable pharmaceuticals; which was ordered to lie on the table; as follows:

At the appropriate place, add the following:

SEC. ___. CLARIFICATION OF STATE AUTHORITY RELATING TO MEDICAID DRUG REBATE AGREEMENTS.

Section 1927 of the Social Security Act (42 U.S.C. 1396r–8) is amended by adding at the end the following:

''(l) RULE OF CONSTRUCTION.—

''(1) IN GENERAL.—With respect to individuals described in paragraph (2) who are enrolled in a State prescription drug program described in paragraph (3), nothing in this section shall be construed as prohibiting a State from—

''(A) directly entering into rebate agreements (on the State's own initiative or under a section 1115 waiver approved by the Secretary before, on, or after the date of enactment of this subsection) that are similar to a rebate agreement described in subsection (b) with a manufacturer for purposes of ensuring the affordability of outpatient prescription drugs in order to provide access to such drugs by such individuals; or

''(B) making prior authorization (that satisfies the requirements of subsection (d) and that does not violate any requirements of this title that are designed to ensure access to medically necessary prescribed drugs for individuals enrolled in the State program under this title) a condition of not participating in such a similar rebate agreement.

''(2) INDIVIDUALS DESCRIBED.—For purposes of paragraph (1), individuals described in this paragraph are individuals—

''(A) whose family income does not exceed 200 percent of the income official poverty line (as defined by the Office of Management and Budget, and revised annually in accordance with section 673(2) of the Omnibus Budget Reconciliation Act of 1981) applicable to a family of the size involved; and

''(B) who are not otherwise eligible for medical assistance under this title.

''(3) STATE PRESCRIPTION DRUG PROGRAM DESCRIBED.—For purposes of paragraph (1), a State prescription drug program described in this paragraph is a State program that was in effect as of July 1, 2002, and under which State appropriated funds substantially paid for the cost of outpatient prescription drugs for individuals described in paragraph (1) who were enrolled in the program.''.

SA 4339. Mr. NICKLES submitted an amendment intended to be proposed to amendment SA 4299 proposed by Mr. REID (for Mr. DORGAN (for himself, Mr. WELLSTONE, Mr. JEFFORDS, Ms. STABENOW, Ms. COLLINS, Mr. LEVIN, Mr. JOHNSON, Mr. MILLER, Mr. DURBIN, Mr. FEINGOLD, and Mr. HARKIN) to the bill (S. 812) to amend the Federal Food, Drug, and Cosmetic Act to provide greater access to affordable pharmaceuticals; which was ordered to lie on the table; as follows:

At the appropriate place, add the following:

SEC. ___. CLARIFICATION OF STATE AUTHORITY RELATING TO MEDICAID DRUG REBATE AGREEMENTS.

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''(A) directly entering into rebate agreements (on the State's own initiative or under a section 1115 waiver approved by the Secretary before, on, or after the date of enactment of this subsection) that are similar to a rebate agreement described in subsection (b) with a manufacturer for purposes of ensuring the affordability of outpatient prescription drugs in order to provide access to such drugs by such individuals; or

''(B) making prior authorization (that satisfies the requirements of subsection (d) and that does not violate any requirements of this title that are designed to ensure access to medically necessary prescribed drugs for individuals enrolled in the State program under this title) a condition of not participating in such a similar rebate agreement.

''(2) INDIVIDUALS DESCRIBED.—For purposes of paragraph (1), individuals described in this paragraph are individuals—

''(A) whose family income does not exceed 200 percent of the income official poverty line (as defined by the Office of Management and Budget, and revised annually in accordance with section 673(2) of the Omnibus Budget Reconciliation Act of 1981) applicable to a family of the size involved; and

''(B) who are not otherwise eligible for medical assistance under this title.

''(3) STATE PRESCRIPTION DRUG PROGRAM DESCRIBED.—For purposes of paragraph (1), a State prescription drug program described in this paragraph is a State program that was in effect as of July 1, 2002, and under which State appropriated funds substantially paid for the cost of outpatient prescription drugs for individuals described in paragraph (1) who were enrolled in the program.''.

SA 4340. Mr. LEAHY submitted an amendment intended to be proposed by him to the bill S. 812, to amend the Federal Food, Drug, and Cosmetic Act to provide greater access to affordable pharmaceuticals; which was ordered to lie on the table; as follows:

At the end insert the following:

TITLE ____—DRUG COMPETITION ACT OF 2002

SEC. ____01. SHORT TITLE.

This title may be cited as the ''Drug Competition Act of 2002''.

SEC. ____02. FINDINGS.

Congress finds that—

(1) prescription drug prices are increasing at an alarming rate and are a major worry of many senior citizens and American families;

(2) there is a potential for companies with patent rights regarding brand-name drugs and companies which could manufacture generic versions of such drugs to enter into financial deals that could tend to restrain trade and greatly reduce competition and increase prescription drug expenditures for American citizens; and

(3) enhancing competition among these companies can significantly reduce prescription drug expenditures for Americans.

SEC. ____03. PURPOSES.

The purposes of this title are—

(1) to provide timely notice to the Department of Justice and the Federal Trade Commission regarding agreements between companies with patent rights regarding branded drugs and companies which could manufacture generic versions of such drugs; and

(2) by providing timely notice, to enhance the effectiveness and efficiency of the enforcement of the antitrust and competition laws of the United States.

SEC. ____04. DEFINITIONS.

In this title:

(1) ANDA.—The term ''ANDA'' means an Abbreviated New Drug Application, as defined under section 201(aa) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(aa)).

(2) ASSISTANT ATTORNEY GENERAL.—The term ''Assistant Attorney General'' means the Assistant Attorney General in charge of the Antitrust Division of the Department of Justice.

(3) BRAND NAME DRUG.—The term ''brand name drug'' means a drug approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)).

(4) BRAND NAME DRUG COMPANY.—The term ''brand name drug company'' means the party that received Food and Drug Administration approval to market a brand name drug pursuant to an NDA, where that drug is the subject of an ANDA, or a party owning or controlling enforcement of any patent listed in the Approved Drug Products With Therapeutic Equivalence Evaluations of the Food and Drug Administration for that drug, under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)).

(5) COMMISSION.—The term ''Commission'' means the Federal Trade Commission.

(6) GENERIC DRUG.—The term ''generic drug'' is a product that the Food and Drug Administration has approved under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)).

(7) GENERIC DRUG APPLICANT.—The term ''generic drug applicant'' means a person who has filed or received approval for an ANDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)).

(8) NDA.—The term ''NDA'' means a New Drug Application, as defined under section 505(b) et seq. of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b) et seq.)

SEC. ____05. NOTIFICATION OF AGREEMENTS.

(a) IN GENERAL.—

(1) REQUIREMENT.—A generic drug applicant that has submitted an ANDA containing a certification under section 505(j)(2)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(2)(vii)(IV)) and a brand name drug company that enter into an agreement described in paragraph (2), prior to the generic drug that is the subject of the application entering the market, shall each file the agreement as required by subsection (b).

(2) DEFINITION.—An agreement described in this paragraph is an agreement regarding—

(A) the manufacture, marketing or sale of the brand name drug that is the subject of the generic drug applicant's ANDA;

(B) the manufacture, marketing or sale of the generic drug that is the subject of the generic drug applicant's ANDA; or

(C) the 180-day period referred to in section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(B)(iv)) as it applies to such ANDA or to any other ANDA based on the same brand name drug.

(b) FILING.—

(1) AGREEMENT.—The generic drug applicant and the brand name drug company entering into an agreement described in subsection (a)(2) shall file with the Assistant Attorney General and the Commission the text of any such agreement, except that the generic drug applicant and the brand-name drug company shall not be required to file an agreement that solely concerns—

(A) purchase orders for raw material supplies;

(B) equipment and facility contracts; or

(C) employment or consulting contracts.

(2) OTHER AGREEMENTS.—The generic drug applicant and the brand name drug company entering into an agreement described in subsection (a)(2) shall file with the Assistant Attorney General and the Commission the text of any other agreements not described in subsection (a)(2) between the generic drug applicant and the brand name drug company which are contingent upon, provide a contingent condition for, or are otherwise related to an agreement which must be filed under this title.

(3) DESCRIPTION.—In the event that any agreement required to be filed by paragraph (1) or (2) has not been reduced to text, both the generic drug applicant and the brand name drug company shall file written descriptions of the non-textual agreement or agreements that must be filed sufficient to reveal all of the terms of the agreement or agreements.

SEC. ____6. FILING DEADLINES.

Any filing required under section ____05 shall be filed with the Assistant Attorney General and the Commission not later than 10 business days after the date the agreements are executed.

SEC. ____07. DISCLOSURE EXEMPTION.

Any information or documentary material filed with the Assistant Attorney General or the Commission pursuant to this title shall be exempt from disclosure under section 552 of title 5, and no such information or documentary material may be made public, except as may be relevant to any administrative or judicial action or proceeding. Nothing in this section is intended to prevent disclosure to either body of Congress or to any duly authorized committee or subcommittee of the Congress.

SEC. ____08. ENFORCEMENT.

(a) CIVIL PENALTY.—Any brand name drug company or generic drug applicant which fails to comply with any provision of this title shall be liable for a civil penalty of not more than $11,000, for each day during which such entity is in violation of this title. Such penalty may be recovered in a civil action brought by the United States, or brought by the Commission in accordance with the procedures established in section 16(a)(1) of the Federal Trade Commission Act (15 U.S.C. 56(a)).

(b) COMPLIANCE AND EQUITABLE RELIEF.—If any brand name drug company or generic drug applicant fails to comply with any provision of this title, the United States district court may order compliance, and may grant such other equitable relief as the court in its discretion determines necessary or appropriate, upon application of the Assistant Attorney General or the Commission. Equitable relief under this subsection may include an order by the district court which renders unenforceable, by the brand name drug company or generic drug applicant failing to file, any agreement that was not filed as required by this title for the period of time during which the agreement was not filed by the company or applicant as required by this title.

SEC. ____09. RULEMAKING.

The Commission, with the concurrence of the Assistant Attorney General and by rule in accordance with section 553 of title 5 United States Code, consistent with the purposes of this title—

(1) may define the terms used in this title;

(2) may exempt classes of persons or agreements from the requirements of this title; and

(3) may prescribe such other rules as may be necessary and appropriate to carry out the purposes of this title.

SEC. ____10. SAVINGS CLAUSE.

Any action taken by the Assistant Attorney General or the Commission, or any failure of the Assistant Attorney General or the Commission to take action, under this title shall not bar any proceeding or any action with respect to any agreement between a brand name drug company and a generic drug applicant at any time under any other provision of law, nor shall any filing under this title constitute or create a presumption of any violation of any antitrust or competition laws.

SEC. ____11. EFFECTIVE DATE.

This title shall—

(1) take effect 30 days after the date of enactment of this title; and

(2) shall apply to agreements described in section ____05 that are entered into 30 days after the date of enactment of this title.

SA 4341. Mr. DAYTON submitted an amendment intended to be proposed by him to the bill S. 812 to amend the Federal Food, Drug, and Cosmetic Act to provide greater access to affordable pharmaceuticals; which was ordered to lie on the table; as follows:

At the end, add the following:

TITLE ____—MEDICARE AMBULANCE PAYMENT REFORM

SEC. ____01. AMBULANCE PAYMENT RATES.

(a) PAYMENT RATES.—

(1) IN GENERAL.—Section 1834(l)(3) of the Social Security Act (42 U.S.C. 1395m(l)(3)) is amended to read as follows:

''(3) PAYMENT RATES.—In the case of any ambulance service furnished under this part in 2003 or any subsequent year, the Secretary shall set the payment rates under the fee schedule for such service at amounts equal to the payment rate under the fee schedule for that service furnished during the previous year, increased by the percentage increase in the Consumer Price Index for all urban consumers (United States city average) for the 12-month period ending with June of the previous year.''.

(2) CONFORMING AMENDMENT.—Section 221(c) of the Medicare, medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (114 Stat. 2763A–487), as enacted into law by section 1(a)(6) of Public Law 106–554, is repealed.

(3) TECHNICAL AMENDMENT.—

(A) IN GENERAL.—Paragraph (8) of section 1834(l) of the Social Security Act (42 U.S.C.

1395m(l)), as added by section 221(a) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (114 Stat. 2763A–487), as enacted into law by section 1(a)(6) of Public Law 106–554, is redesignated as paragraph (9).

(B) EFFECTIVE DATE.—The amendment made by subparagraph (A) shall take effect as if included in the enactment of such section 221(a).

(b) USE OF MEDICAL CONDITIONS FOR CODING AMBULANCE SERVICES.—Section 1834(l)(7) of the Social Security Act (42 U.S.C. 1395m(l)(7)) is amended to read as follows:

''(7) CODING SYSTEM.—

''(A) IN GENERAL.—The Secretary shall, in accordance with section 1173(c)(1)(B), establish a system or systems for the coding of claims for ambulance services for which payment is made under this subsection, including a code set specifying the medical condition of the individual who is transported and the level of service that is appropriate for the transportation of an individual with that medical condition.

''(B) MEDICAL CONDITIONS.—The code set established under subparagraph (A) shall—

''(i) take into account the list of medical conditions developed in the course of the negotiated rulemaking process conducted under paragraph (1); and

''(ii) notwithstanding any other provision of law, be adopted as a standard code set under section 1173(c).''.

SEC. ___02. PRUDENT LAYPERSON STANDARD FOR EMERGENCY AMBULANCE SERVICES UNDER MEDICARE AND MEDICAID.

(a) AMBULANCE SERVICES FOR MEDICARE FEE-FOR-SERVICE BENEFICIARIES.—Section 1861(s)(7) of the Social Security Act (42 U.S.C. 1395x(s)(7)) is amended by inserting before the semicolon at the end the following: '', except that such regulations shall not fail to treat ambulance services as medical and other health services solely because the ultimate diagnosis of the individual receiving the ambulance services results in the conclusion that ambulance services were not necessary, as long as the request for ambulance services is made after the sudden onset of a medical condition that would be classified as an emergency medical condition (as defined in section 1852(d)(3)(B)).''.

(b) AMBULANCE SERVICES FOR MEDICARE+CHOICE ENROLLEES.—Section 1852(d)(3)(A) of the Social Security Act (42 U.S.C. 1395w–22(d)(3)(A)) is amended by inserting ''(including the services described in section 1861(s)(7))'' after ''outpatient services'' in the matter preceding clause (i).

(c) AMBULANCE SERVICES IN MEDICAID MANAGED CARE PLANS.—Section 1932(b)(2)(B) of the Social Security Act (42 U.S.C. 1396u–2(b)(2)(B)) is amended by inserting ''(including the services described in section 1861(s)(7) (if covered by the State plan))'' after ''outpatient services'' in the matter preceding clause (i).

(d) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to services provided on and after the date of enactment of the Act.

SA 4342. Mr. FRIST submitted an amendment intended to be proposed by him to the bill S. 812, to amend the Federal Food, Drug, and Cosmetic Act to provide greater access to affordable pharmaceuticals; which was ordered to lie on the table; as follows:

Strike section 7.

SA 4343. Mr. FRIST submitted an amendment intended to be proposed by him to the bill S. 812, to amend the Federal Food, Drug, and Cosmetic Act to provide greater access to affordable pharmaceuticals; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

TITLE ___—IMPROVED VACCINE AFFORDABILITY AND AVAILABILITY

SEC. ___01. SHORT TITLE.

This title may be cited as the ''Improved Vaccine Affordability and Availability Act''.

Subtitle A—State Vaccine Grants

SEC. ___11. AVAILABILITY OF INFLUENZA VACCINE.

Section 317(j) of the Public Health Service Act (42 U.S.C. 247b(j)) is amended by adding at the end the following:

''(3)(A) For the purpose of carrying out activities relating to influenza vaccine under the immunization program under this subsection, there are authorized to be appropriated such sums as may be necessary for each of fiscal years 2003 and 2004. Such authorization shall be in addition to amounts available under paragraphs (1) and (2) for such purpose.

''(B) The authorization of appropriations established in subparagraph (A) shall not be effective for a fiscal year unless the total amount appropriated under paragraphs (1) and (2) for the fiscal year is not less than such total for fiscal year 2000.

''(C) The purposes for which amounts appropriated under subparagraph (A) are available to the Secretary include providing for improved State and local infrastructure for influenza immunizations under this subsection in accordance with the following:

''(i) Increasing influenza immunization rates in populations considered by the Secretary to be at high risk for influenza-related complications and in their contacts.

''(ii) Recommending that health care providers actively target influenza vaccine that is available in September, October, and November to individuals who are at increased risk for influenza-related complications and to their contacts.

''(iii) Providing for the continued availability of influenza immunizations through December of such year, and for additional periods to the extent that influenza vaccine remains available.

''(iv) Encouraging States, as appropriate, to develop contingency plans (including plans for public and professional educational activities) for maximizing influenza immunizations for high-risk populations in the event of a delay or shortage of influenza vaccine.

''(D) The Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions of the Senate, periodic reports describing the activities of the Secretary under this subsection regarding influenza vaccine. The first such report shall be submitted not later than June 6, 2003, the second report shall be submitted not later than June 6, 2004, and subsequent reports shall be submitted biennially thereafter.''.

SEC. ___12. PROGRAM FOR INCREASING IMMUNIZATION RATES FOR ADULTS AND ADOLESCENTS; COLLECTION OF ADDITIONAL IMMUNIZATION DATA.

(a) ACTIVITIES OF CENTERS FOR DISEASE CONTROL AND PREVENTION.—Section 317(j) of the Public Health Service Act (42 U.S.C. 247b(j)), as amended by section ___11, is further amended by adding at the end the following:

''(4)(A) For the purpose of carrying out activities to increase immunization rates for adults and adolescents through the immunization program under this subsection, and for the purpose of carrying out subsection (k)(2), there are authorized to be appropriated $50,000,000 for fiscal year 2003, and such sums as may be necessary for each of the fiscal years 2004 through 2006. Such authorization is in addition to amounts available under paragraphs (1), (2), and (3) for such purposes.

''(B) In expending amounts appropriated under subparagraph (A), the Secretary shall give priority to adults and adolescents who are medically underserved and are at risk for vaccine-preventable diseases, including as appropriate populations identified through projects under subsection (k)(2)(E).

''(C) The purposes for which amounts appropriated under subparagraph (A) are available include (with respect to immunizations for adults and adolescents) the payment of the costs of storing vaccines, outreach activities to inform individuals of the availability of the immunizations, and other program expenses necessary for the establishment or operation of immunization programs carried out or supported by States or other public entities pursuant to this subsection.

''(5) The Secretary shall annually submit to Congress a report that—

''(A) evaluates the extent to which the immunization system in the United States has been effective in providing for adequate immunization rates for adults and adolescents, taking into account the applicable year 2010 health objectives established by the Secretary regarding the health status of the people of the United States; and

''(B) describes any issues identified by the Secretary that may affect such rates.

''(6) In carrying out this subsection and paragraphs (1) and (2) of subsection (k), the Secretary shall consider recommendations regarding immunizations that are made in reports issued by the Institute of Medicine.''.

(b) RESEARCH, DEMONSTRATIONS, AND EDUCATION.—Section 317(k) of the Public Health Service Act (42 U.S.C. 247b(k)) is amended—

(1) by redesignating paragraphs (2) through (4) as paragraphs (3) through (5), respectively; and

(2) by inserting after paragraph (1) the following:

''(2) The Secretary, directly and through grants under paragraph (1), shall provide for a program of research, demonstration projects, and education in accordance with the following:

''(A) The Secretary shall coordinate with public and private entities (including nonprofit private entities), and develop and disseminate guidelines, toward the goal of ensuring that immunizations are routinely offered to adults and adolescents by public and private health care providers.

''(B) The Secretary shall cooperate with public and private entities to obtain information for the annual evaluations required in subsection (j)(5)(A).

''(C) The Secretary shall (relative to fiscal year 2001) increase the extent to which the Secretary collects data on the incidence, prevalence, and circumstances of diseases and adverse events that are experienced by adults and adolescents and may be associated with immunizations, including collecting data in cooperation with commercial laboratories.

''(D) The Secretary shall ensure that the entities with which the Secretary cooperates for purposes of subparagraphs (A) through (C) include managed care organizations, community-based organizations that provide health services, and other health care providers.

''(E) The Secretary shall provide for projects to identify racial and ethnic minority groups and other health disparity populations for which immunization rates for adults and adolescents are below such rates for the general population, and to determine the factors underlying such disparities.''.

SEC. ___13. IMMUNIZATION AWARENESS.

(a) DEVELOPMENT OF INFORMATION CONCERNING MENINGITIS.—

(1) IN GENERAL.—The Secretary of Health and Human Services, in consultation with the Director of the Centers for Disease Control and Prevention, shall develop and make available to entities described in paragraph (2) information concerning bacterial meningitis and the availability and effectiveness of vaccinations for populations targeted by the Advisory Committee on Immunization Practices (an advisory committee established by the Secretary of Health and Human Services, acting through the Centers for Disease Control and Prevention).

(2) ENTITIES.—An entity is described in this paragraph if the entity—

(A) is—

(i) a college or university; or

(ii) any other facility with a setting similar to a dormitory that houses age-appropriate populations for whom the Advisory Committee on Immunization Practices recommends such a vaccination; and

(B) is determined appropriate by the Secretary of Health and Human Services.

(b) DEVELOPMENT OF INFORMATION CONCERNING HEPATITIS.—

(1) IN GENERAL.—The Secretary of Health and Human Services, in consultation with the Director of the Centers for Disease Control and Prevention, shall develop and make available to entities described in paragraph (2) information concerning hepatitis A and B and the availability and effectiveness of vaccinations with respect to such diseases.

(2) ENTITIES.—An entity is described in this paragraph if the entity—

(A) is—

(i) a health care clinic that serves individuals diagnosed as being infected with HIV or as having other sexually transmitted diseases;

(ii) an organization or business that counsels individuals about international travel or who arranges for such travel;

(iii) a police, fire or emergency medical services organization that responds to natural or man-made disasters or emergencies;

(iv) a prison or other detention facility;

(v) a college or university; or

(vi) a public health authority or children's health service provider in areas of intermediate or high endemicity for hepatitis A as defined by the Centers for Disease Control and Prevention; and

(B) is determined appropriate by the Secretary of Health and Human Services.

SEC. ___14. SUPPLY OF VACCINES.

(a) IN GENERAL.—The Secretary of Health and Human Services, acting through the Director of the Centers for Disease Control and Prevention, shall prioritize, acquire, and maintain a supply of such prioritized vaccines sufficient to provide vaccinations throughout a 6-month period.

(b) PROCEEDS.—Any proceeds received by the Secretary of Health and Human Services from the sale of vaccines contained in the supply described in subsection (a), shall be available to the Secretary for the purpose of purchasing additional vaccines for the supply. Such proceeds shall remain available until expended.

(c) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated for the purpose of carrying out subsection (a) such sums as may be necessary for each of fiscal years 2003 through 2008.

Subtitle B—Vaccine Injury Compensation Program

SEC. ___21. ADMINISTRATIVE REVISION OF VACCINE INJURY TABLE.

Section 2114 of the Public Health Service Act (42 U.S.C. 300aa–14) is amended—

(1) in subsection (c), by striking paragraph (1) and inserting the following:

''(1) The Secretary may promulgate regulations to modify in accordance with paragraph (3) the Vaccine Injury Table. In promulgating such regulations, the Secretary shall provide for notice and for at least 60 days opportunity for public comment.''; and

(2) in subsection (d), by striking ''90 days'' and inserting ''60 days''.

SEC. ___22. EQUITABLE RELIEF.

Section 2111(a)(2)(A) of the Public Health Service Act (42 U.S.C. 300aa–11(a)(2)(A)) is amended by striking ''No person'' and all that follows through ''and—'' and inserting the following: ''No person may bring or maintain a civil action against a vaccine administrator or manufacturer in a State or Federal court for damages arising from, or equitable relief relating to, a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988 and no such court may award damages or equitable relief for any such vaccine-related injury or death, unless the person proves past or present physical injury and a timely petition has been filed, in accordance with section 2116 for compensation under the Program for such injury or death and—''.

SEC. ___23. PARENT OR OTHER THIRD PARTY PETITIONS FOR COMPENSATION.

(a) LIMITATIONS ON DERIVATIVE PETITIONS.—Section 2111(a)(2) of the Public Health Service Act (42 U.S.C. 300aa–11(a)(2)) is amended—

(1) in subparagraph (B), by inserting ''or (B)'' after ''subparagraph (A)'';

(2) by redesignating subparagraph (B) as subparagraph (C); and

(3) by inserting after subparagraph (A) the following:

''(B)(i) No parent, legal guardian, or spouse (referred to in this title as a parent or other third party) may bring or maintain a civil action against a vaccine administrator or manufacturer in a Federal or State court for damages or equitable relief relating to a vaccine-related injury or death, including damages for loss of consortium, society, companionship, or services, loss of earnings, medical or other expenses, and emotional distress, and no court may award damages or equitable relief in such an action, unless—

''(I) the person who sustained the underlying vaccine-related injury or death upon which such parent's or other third party's claim is premised has, in accordance with section 2112, been awarded compensation in a final judgment of the United States Court of Federal Claims and such judgment is subject to no further appeal or review;

''(II) such parent or other third party timely filed a derivative petition, in accordance with section 2116; and

''(III)(aa) the United States Court of Federal Claims has issued judgment under section 2112 on the derivative petition, and such parent or other third party elects under section 2121(a) to file a civil action; or

''(bb) such parent or other third party elects to withdraw such derivative petition under section 2121(b) or such petition is considered withdrawn under such section.

''(ii) Any civil action brought in accordance with this subparagraph shall be subject to the standards and procedures set forth in sections 2122 and 2123, regardless of whether the action arises directly from a vaccine-related injury or death associated with the administration of a vaccine. In a case in which the person who sustained the underlying vaccine-related injury or death upon which such parent's or other third party's civil action is premised elects under section 2121(a) to receive the compensation awarded, such parent or other third party may not bring a civil action for damages or equitable relief, and no court may award damages or equitable relief, for any injury or loss of the type set forth in section 2115(a) or that might in any way overlap with or otherwise duplicate compensation of the type available under section 2115(a).''.

(b) ELIGIBLE PERSONS.—Section 2111(a)(9) of the Public Health Service Act (42 U.S.C. 300aa–11(a)(9)) is amended by striking the period and inserting ''and to a parent or other third party to the extent such parent or other third party seeks damages or equitable relief relating to a vaccine-related injury or death sustained by a person who is qualified to file a petition for compensation under the Program.''.

(c) PETITIONERS.—Section 2111(b) of the Public Health Service Act (42 U.S.C. 300aa–11(b)) is amended—

(1) in paragraph (1)—

(A) in subparagraph (A), by striking ''(B)'' and inserting ''(C)'';

(B) by redesignating subparagraph (B) as subparagraph (C); and

(C) by inserting after subparagraph (A) the following:

''(B) Except as provided in subparagraph (C), any parent or other third party with respect to a person—

''(i) who has sustained a vaccine-related injury or death;

''(ii) who has filed a petition for compensation under the Program (or whose legal representative has filed such a petition as authorized in subparagraph (A)); and

''(iii) who has, in accordance with section 2112, been awarded compensation in a final judgment of the United States Court of Federal Claims that is subject to no further appeal or review;

may, if such parent or other third party meets the requirements of subsection (d), file a derivative petition under this section.''; and

(2) in paragraph (2)—

(A) by inserting ''by or on behalf of the person who sustained the vaccine-related injury or death'' after ''filed''; and

(B) by adding at the end the following: ''A parent or other third party may file only 1 derivative petition with respect to each administration of a vaccine.''.

(d) DERIVATIVE PETITION CONTENTS.—Section 2111 of the Public Health Service Act (42 U.S.C. 300aa–11) is amended—

(1) by redesignating subsections (d) and (e) as subsections (e) and (f), respectively; and

(2) by inserting after subsection (c) the following:

''(d) DERIVATIVE PETITIONS.—

''(1) If the parent or other third party with respect to the person who sustained the vaccine-related injury or death seeks compensation under the Program, such parent or other third party shall file a timely derivative petition for compensation under the Program in accordance with this section.

''(2) Such a derivative petition shall contain—

''(A) except for records that are unavailable as described in subsection (c)(3), an affidavit, and supporting documentation, demonstrating that—

''(i) such person was, in accordance with section 2112, previously awarded compensation for the underlying vaccine-related injury or death upon which such parent's or other third party's derivative petition is premised in a final judgment of the United States Court of Federal Claims and such judgment is subject to no further appeal or review;

''(ii) the derivative petition was filed not later than 60 days after the date on which such judgment became final and subject to no further appeal or review;

''(iii) such parent or other third party suffered a loss compensable under section 2115(b) as a result of the vaccine-related injury or death sustained by such person; and

''(iv) such parent or other third party has not previously collected an award or settlement of a civil action for damages for such loss; and

''(B) records establishing such parent's or other third party's relationship to the person who sustained the vaccine-related injury or death.''.

(e) DETERMINATION OF ELIGIBILITY FOR COMPENSATION.—Section 2113(a)(1) of the Public Health Service Act (42 U.S.C. 300aa–13(a)(1)) is amended—

(1) in subparagraph (A), by inserting ''or, as applicable, section 2111(d)'' before the comma; and

(2) in subparagraph (B), by inserting ''or, as applicable, that the injury or loss described in the derivative petition is due to factors unrelated to the vaccine-related injury or death'' after ''the petition''.

(f) COMPENSATION.—Section 2115 of the Public Health Service Act (42 U.S.C. 300aa–15) is amended—

(1) by redesignating subsections (b) through (j) as subsections (c) through (k), respectively;

(2) by inserting after subsection (a) the following:

''(b) DERIVATIVE PETITIONS.—Compensation awarded under the Program to a parent or other third party who files a derivative petition under section 2111 for a loss sustained as a result of a vaccine-related injury or death sustained by the injured party shall include compensation, if any, for loss of consortium, society, companionship, or services, in an amount not to exceed the lesser of $250,000 or the total amount of compensation awarded to the person who sustained the underlying vaccine-related injury or death.'';

(3) in subsection (e)(2), as so redesignated by paragraph (1)—

(A) by striking ''(2) and (3)'' and inserting ''(2), (3), and (4)''; and

(B) by inserting ''and subsection (b),'' after ''(a),'';

(4) in subsection (g), as so redesignated by paragraph (1), in paragraph (4)(B), by striking ''subsection (j)'' and inserting ''subsection (k)'';

(5) in subsection (j), as so redesignated by paragraph (1)—

(A) in paragraph (1), by striking ''subsection (j)'' and inserting ''subsection (k)''; and

(B) in paragraph (2), by inserting '', or to a parent or other third party with respect to a person who sustained a vaccine-related injury or death,'' after ''death''; and

(6) in subsection (k), as so redesignated by paragraph (1), by striking ''subsection (f)(4)(B)'' and inserting ''subsection (g)(4)(B)''.

SEC. ___24. JURISDICTION TO DISMISS ACTIONS IMPROPERLY BROUGHT.

Section 2111(a)(3) of the Public Health Service Act (42 U.S.C. 300aa–11(a)(3)) is amended by adding at the end the following: ''If any civil action which is barred under subparagraph (A) or (B) of paragraph (2) is filed or maintained in a State court, or any vaccine administrator or manufacturer is made a party to any civil action brought in State court (other than a civil action which may be brought under paragraph (2)) for damages or equitable relief for a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, the civil action may be removed by the defendant or defendants to the United States Court of Federal Claims, which shall have jurisdiction over such civil action, and which shall dismiss such action. The notice required by section 1446 of title 28, United States Code, shall be filed with the United States Court of Federal Claims, and that court shall proceed in accordance with sections 1446 through 1451 of title 28, United States Code.''.

SEC. ___25. APPLICATION.

Section 2111(a)(9) of the Public Health Service Act (42 U.S.C. 300aa–11(a)(9)) is amended by striking ''This'' and inserting ''Except as provided in paragraph (2), this''.

SEC. ___26. CLARIFICATION OF WHEN INJURY IS CAUSED BY FACTOR UNRELATED TO ADMINISTRATION OF VACCINE.

Section 2113(a)(2)(B) of the Public Health Service Act (42 U.S.C. 300aa–13(a)(2)(B)) is amended—

(1) by inserting ''structural lesions, genetic disorders,'' after ''and related anoxia),'';

(2) by inserting ''(without regard to whether the cause of the infection, toxin, trauma, structural lesion, genetic disorder, or metabolic disturbance is known)'' after ''metabolic disturbances''; and

(3) by striking ''but'' and inserting ''and''.

SEC. ___27. INCREASE IN AWARD IN THE CASE OF A VACCINE-RELATED DEATH AND FOR PAIN AND SUFFERING.

Section 2115(a) of the Public Health Service Act (42 U.S.C. 300aa–15(a)) is amended—

(1) in paragraph (2), by striking ''$250,000'' and inserting ''$350,000''; and

(2) in paragraph (4), by striking ''$250,000'' and inserting ''$350,000''.

SEC. ___28. BASIS FOR CALCULATING PROJECTED LOST EARNINGS.

Section 2115(a)(3)(B) of the Public Health Service Act (42 U.S.C. 300aa–15(a)(3)(B)) is amended by striking ''loss of earnings'' and all that follows and inserting the following: ''loss of earnings determined on the basis of the annual estimate of the average (mean) gross weekly earnings of wage and salary workers age 18 and over (excluding the incorporated self-employed) in the private nonfarm sector (which includes all industries other than agricultural production crops and livestock), as calculated annually by the Bureau of Labor Statistics from the quarter sample data of the Current Population Survey, or as calculated by such similar method as the Secretary may prescribe by regulation, less appropriate taxes and the average cost of a health insurance policy, as determined by the Secretary.''.

SEC. ___29. ALLOWING COMPENSATION FOR FAMILY COUNSELING EXPENSES AND EXPENSES OF ESTABLISHING GUARDIANSHIP.

(a) FAMILY COUNSELING EXPENSES IN POST-1988 CASES.—Section 2115(a) of the Public Health Service Act (42 U.S.C. 300aa–15(a)) is amended by adding at the end to following:

''(5) Actual unreimbursable expenses that have been or will be incurred for family counseling as is determined to be reasonably necessary and that result from the vaccine-related injury from which the petitioner seeks compensation.''.

(b) EXPENSES OF ESTABLISHING GUARDIANSHIPS IN POST-1988 CASES.—Section 2115(a) of the Public Health Service Act (42 U.S.C. 300aa–15(a)), as amended by subsection (a), is further amended by adding at the end the following:

''(6) Actual unreimbursable expenses that have been, or will be reasonably incurred to establish and maintain a guardianship or conservatorship for an individual who has suffered a vaccine-related injury, including attorney fees and other costs incurred in a proceeding to establish and maintain such guardianship or conservatorship.''.

(c) CONFORMING AMENDMENT FOR CASES FROM 1988 AND EARLIER.—Section 2115 of the Public Health Service Act (42 U.S.C. 300aa–15) is amended in subsection (c), as so redesignated by section ___23(f)—

(1) in paragraph (2), by striking ''and'' at the end;

(2) in paragraph (3), by striking ''(e)'' and inserting ''(f))'';

(3) by redesignating paragraph (3) as paragraph (5); and

(4) by inserting after paragraph (2), the following:

''(3) family counseling expenses (as provided for in paragraph (5) of subsection (a));

''(4) expenses of establishing guardianships (as provided for in paragraph (6) of subsection (a)); and''.

SEC. ___30. ALLOWING PAYMENT OF INTERIM COSTS.

Section 2115 of the Public Health Service Act (42 U.S.C. 300aa–15) is amended in subsection (f), as so redesignated by section ___23(f), by adding at the end the following:

''(4) A special master or court may make an interim award of costs if—

''(A) the case involves a vaccine administered on or after October 1, 1988;

''(B) the special master or court has determined whether or not the petitioner is entitled to compensation under the Program;

''(C) the award is limited to other costs (within the meaning of paragraph (1)(B)) incurred in the proceeding; and

''(D) the petitioner provides documentation verifying the expenditure of the amount for which compensation is sought.''.

SEC. ___31. PROCEDURE FOR PAYING ATTORNEYS' FEES.

Section 2115 of the Public Health Service Act (42 U.S.C. 300aa–15), is amended in subsection (f), as so redesignated by section ___23(f) and amended by section ___30, by adding at the end the following:

''(5) When a special master or court awards attorney fees or costs under paragraph (1) or (4), it may order that such fees or costs be payable solely to the petitioner's attorney if—

''(A) the petitioner expressly consents; or

''(B) the special master or court determines, after affording to the Secretary and to all interested persons the opportunity to submit relevant information, that—

''(i) the petitioner cannot be located or refuses to respond to a request by the special master or court for information, and there is no practical alternative means to ensure that the attorney will be reimbursed for such fees or costs expeditiously; or

''(ii) there are otherwise exceptional circumstances and good cause for paying such fees or costs solely to the petitioner's attorney.''.

SEC. ___32. EXTENSION OF STATUTE OF LIMITATIONS.

(a) GENERAL RULE.—Section 2116(a) of the Public Health Service Act (42 U.S.C. 300aa–16(a)) is amended—

(1) in paragraph (2) by striking ''36 months'' and inserting ''6 years''; and

(2) in paragraph (3), by striking ''48 months'' and inserting ''6 years''.

(b) CLAIMS BASED ON REVISIONS TO TABLE.—Section 2116 of the Public Health Service Act (42 U.S.C. 300aa–16) is amended by striking subsection (b) and inserting the following:

''(b) EFFECT OF REVISED TABLE.—If at any time the Vaccine Injury Table is revised and the effect of such revision is to make an individual eligible for compensation under the program, where, before such revision, such individual was not eligible for compensation under the program, or to significantly increase the likelihood that an individual will be able to obtain compensation under the program, such person may, and shall before filing a civil action for equitable relief or monetary damages, notwithstanding section 2111(b)(2), file a petition for such compensation if—

''(1) the vaccine-related death or injury with respect to which the petition is filed occurred not more than 8 years before the effective date of the revision of the table; and

''(2) either—

''(A) the petition satisfies the conditions described in subsection (a); or

''(B) the date of the occurrence of the first symptom or manifestation of onset of the injury occurred more than 4 years before the petition is filed, and the petition is filed not more than 2 years after the effective date of the revision of the table.''.

(c) DERIVATIVE PETITIONS.—Section 2116 of the Public Health Service Act (42 U.S.C. 300aa–16) is amended by adding at the end the following:

''(d) DERIVATIVE PETITIONS.—No derivative petition may be filed for compensation under the Program later than 60 days after the date on which the United States Court of Federal Claims has entered final judgment and the time for all further appeal or review has expired on the underlying claim of the person who sustained the vaccine-related injury or death upon which the derivative petition is premised.''.

(d) TIMELY RESOLUTIONS OF CLAIMS.—

(1) SPECIAL MASTER DECISION.—Section 2112(d)(3)(A) of the Public Health Service Act (42 U.S.C. 300aa–12(d)(3)(A)) is amended by adding at the end the following: ''For purposes of this subparagraph, the petition shall be deemed to be filed on the date on which all petition contents and supporting documents required under section 2111(c) and, when applicable, section 2111(d) and the Vaccine Rules of the United States Court of Federal Claims, such as an affidavit and supporting documentation, are served on the Secretary and filed with the clerk of the United States Court of Federal Claims.''.

(2) COURT OF FEDERAL CLAIMS DECISION.—Section 2121(b) of the Public Health Service Act (42 U.S.C. 300aa–21(b)) is amended by adding at the end the following: ''For purposes of this subsection, the petition shall be deemed to be filed on the date on which all petition contents and supporting documents required under section 2111(c) and, when applicable, section 2111(d) and the Vaccine Rules of the United States Court of Federal Claims, such as an affidavit and supporting documentation, are served on the Secretary and filed with the clerk of the United States Court of Federal Claims.''.

SEC. ___33. ADVISORY COMMISSION ON CHILDHOOD VACCINES.

(a) SELECTION OF PERSONS INJURED BY VACCINES AS PUBLIC MEMBERS.—Section 2119(a)(1)(B) of the Public Health Service Act (42 U.S.C. 300aa–19(a)(1)(B)) is amended by striking ''of whom'' and all that follows and inserting the following: ''of whom 1 shall be the legal representative of a child who has suffered a vaccine-related injury or death, and at least 1 other shall be either the legal representative of a child who has suffered a vaccine-related injury or death or an individual who has personally suffered a vaccine-related injury.''.

(b) MANDATORY MEETING SCHEDULE ELIMINATED.—Section 2119(c) of the Public Health Service Act (42 U.S.C. 300aa–19(c)) is amended by striking ''not less often than four times per year and''.

SEC. ___34. CLARIFICATION OF STANDARDS OF RESPONSIBILITY.

(a) GENERAL RULE.—Section 2122(a) of the Public Health Service Act (42 U.S.C. 300aa–22(a)) is amended by striking ''and (e) State law shall apply to a civil action brought for damages'' and inserting ''(d), and (f) State law shall apply to a civil action brought for damages or equitable relief''; and

(b) UNAVOIDABLE ADVERSE SIDE EFFECTS.—Section 2122(b)(1) of the Public Health Service Act (42 U.S.C. 300aa–22(b)(1)) is amended by inserting ''or equitable relief'' after ''for damages''.

(c) DIRECT WARNINGS.—Section 2122(c) of the Public Health Service Act (42 U.S.C. 300aa–22(c)) is amended by inserting ''or equitable relief'' after ''for damages''.

(d) CONSTRUCTION.—Section 2122(d) of the Public Health Service Act (42 U.S.C. 300aa–22(d)) is amended—

(1) by inserting ''or equitable relief'' after ''for damages''; and

(2) by inserting ''or relief'' after ''which damages''.

(e) PAST OR PRESENT PHYSICAL INJURY.—Section 2122 of the Public Health Service Act (42 U.S.C. 300aa–22) is amended—

(1) by redesignating subsections (d) and (e) as subsections (e) and (f), respectively; and

(2) by inserting after subsection (c) the following:

''(d) PAST OR PRESENT PHYSICAL INJURY.—No vaccine manufacturer or vaccine administrator shall be liable in a civil action brought after October 1, 1988, for equitable or monetary relief absent proof of past or present physical injury from the administration of a vaccine, nor shall any vaccine manufacturer or vaccine administrator be liable in any such civil action for claims of medical monitoring, or increased risk of harm.''.

SEC. ___35. CLARIFICATION OF DEFINITION OF MANUFACTURER.

Section 2133(3) of the Public Health Service Act (42 U.S.C. 300aa–33(3)) is amended—

(1) in the first sentence, by striking ''under its label any vaccine set forth in the Vaccine Injury Table'' and inserting ''any vaccine set forth in the Vaccine Injury table, including any component or ingredient of any such vaccine''; and

(2) in the second sentence, by inserting ''including any component or ingredient of any such vaccine'' before the period.

SEC. ___36. CLARIFICATION OF DEFINITION OF VACCINE-RELATED INJURY OR DEATH.

Section 2133(5) of the Public Health Service Act (42 U.S.C. 300aa–33(5)) is amended by adding at the end the following: ''For purposes of the preceding sentence, an adulterant or contaminant shall not include any component or ingredient listed in a vaccine's product license application or product label.''.

SEC. ___37. CLARIFICATION OF DEFINITION OF VACCINE.

Section 2133 of the Public Health Service Act (42 U.S.C. 300aa–33) is amended by adding at the end the following:

''(7) The term 'vaccine' means any preparation or suspension, including a preparation or suspension containing an attenuated or inactive microorganism or subunit thereof or toxin, developed or administered to produce or enhance the body's immune response to a disease or diseases and includes all components and ingredients listed in the vaccines's product license application and product label.''.

SEC. ___38. AMENDMENTS TO VACCINE INJURY COMPENSATION TRUST FUND.

(a) EXPANSION OF COMPENSATED LOSS.—Section 9510(c)(1)(A) of the Internal Revenue Code of 1986 is amended by inserting '', or related loss,'' after ''death''.

(b) INCREASE IN LIMIT ON ADMINISTRATIVE EXPENSES.—Subparagraph (B) of section 9510(c)(1) of the Internal Revenue Code of 1986 is amended—

(1) by striking ''(but not in excess of the base amount of $9,500,000 for any fiscal year)''; and

(2) by striking the period and inserting '', provided that such administrative costs shall not exceed the greater of—

''(i) the base amount of $9,500,000,

''(ii) 125 percent of the base amount for any fiscal year in which the total number of claims pending under such subtitle exceeds 150 percent of the average number of claims pending in the preceding 5 years,

''(iii) 175 percent of the base amount for any fiscal year in which the total number of claims pending under such subtitle exceeds 200 percent of the average number of claims pending in the preceding 5 years,

''(iv) 225 percent of the base amount for any fiscal year in which the total number of claims pending under such subtitle exceeds 250 percent of the average number of claims pending in the preceding 5 years, or

''(v) 275 percent of the base amount for any fiscal year in which the total number of claims pending under such subtitle exceeds 300 percent of the average number of claims pending in the preceding 5 years.''.

(c) CONFORMING AMENDMENT.—Section 9510(c)(1)(A) of the Internal Revenue Code of 1986 is amended by striking ''October 18, 2000'' and inserting ''the date of enactment of the Improved Vaccine Affordability and Availability Act''.

SEC. ___39. ONGOING REVIEW OF CHILDHOOD VACCINE DATA.

Part C of title XXI of the Public Health Service Act (42 U.S.C. 300a–25 et seq.) is amended by adding at the end the following:

''SEC. 2129. ONGOING REVIEW OF CHILDHOOD VACCINE DATA.

''(a) IN GENERAL.—Not later than 6 months after the date of enactment of this section, the Secretary shall enter into a contract with the Institute of Medicine of the National Academy of Science under which the Institute shall conduct an ongoing, comprehensive review of new scientific data on childhood vaccines (according to priorities agreed upon from time to time by the Secretary and the Institute of Medicine).

''(b) REPORTS.—Not later than 3 years after the date on which the contract is entered into under subsection (a), the Institute of Medicine shall submit to the Secretary a report on the findings of studies conducted, including findings as to any adverse events associated with childhood vaccines, including conclusions concerning causation of adverse events by such vaccines, and other appropriate recommendations, based on such findings and conclusions.

''(c) FAILURE TO ENTER INTO CONTRACT.—If the Secretary and the Institute of Medicine are unable to enter into the contract described in subsection (a), the Secretary shall enter into a contract with another qualified nongovernmental scientific organization for the purposes described in subsections (a) and (b).

''(d) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated such sums as may be necessary for each of fiscal years 2003, 2004, 2005 and 2006.''.

SEC. ___40. PENDING ACTIONS.

The amendments made by this title shall apply to all actions or proceedings pending on or after the date of enactment of this Act, unless a court of competent jurisdiction has entered judgment (regardless of whether the time for appeal has expired) in such action or proceeding disposing of the entire action or proceeding.

SEC. ___41. REPORT.

Not later than 1 year after the date of enactment of this Act, and annually thereafter, the Advisory Commission on Childhood Vaccines shall report to the Secretary of Health and Human Services regarding the status of the Vaccine Injury Compensation Trust Fund, and shall make recommendations to the Secretary regarding the allocation of funds from the Vaccine Injury Compensation Trust Fund.

SA 4344. Mr. FRIST submitted an amendment intended to be proposed to amendment SA 4299 proposed by Mr. REID (for Mr. DORGAN (for himself, Mr. WELLSTONE, Mr. JEFFORDS, Ms. STABENOW, Ms. COLLINS, Mr. LEVIN, Mr.

JOHNSON, Mr. MILLER, Mr. DURBIN, Mr. FEINGOLD, and Mr. HARKIN)) to the bill (S. 812) to amend the Federal Food, Drug, and Cosmetic Act to provide greater access to affordable pharmaceuticals; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

TITLE ____—IMPROVED VACCINE AFFORDABILITY AND AVAILABILITY

SEC. ___01. SHORT TITLE.

This title may be cited as the ''Improved Vaccine Affordability and Availability Act''.

Subtitle A—State Vaccine Grants

SEC. ___11. AVAILABILITY OF INFLUENZA VACCINE.

Section 317(j) of the Public Health Service Act (42 U.S.C. 247b(j)) is amended by adding at the end the following:

''(3)(A) For the purpose of carrying out activities relating to influenza vaccine under the immunization program under this subsection, there are authorized to be appropriated such sums as may be necessary for each of fiscal years 2003 and 2004. Such authorization shall be in addition to amounts available under paragraphs (1) and (2) for such purpose.

''(B) The authorization of appropriations established in subparagraph (A) shall not be effective for a fiscal year unless the total amount appropriated under paragraphs (1) and (2) for the fiscal year is not less than such total for fiscal year 2000.

''(C) The purposes for which amounts appropriated under subparagraph (A) are available to the Secretary include providing for improved State and local infrastructure for influenza immunizations under this subsection in accordance with the following:

''(i) Increasing influenza immunization rates in populations considered by the Secretary to be at high risk for influenza-related complications and in their contacts.

''(ii) Recommending that health care providers actively target influenza vaccine that is available in September, October, and November to individuals who are at increased risk for influenza-related complications and to their contacts.

''(iii) Providing for the continued availability of influenza immunizations through December of such year, and for additional periods to the extent that influenza vaccine remains available.

''(iv) Encouraging States, as appropriate, to develop contingency plans (including plans for public and professional educational activities) for maximizing influenza immunizations for high-risk populations in the event of a delay or shortage of influenza vaccine.

''(D) The Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions of the Senate, periodic reports describing the activities of the Secretary under this subsection regarding influenza vaccine. The first such report shall be submitted not later than June 6, 2003, the second report shall be submitted not later than June 6, 2004, and subsequent reports shall be submitted biennially thereafter.''.

SEC. ___12. PROGRAM FOR INCREASING IMMUNIZATION RATES FOR ADULTS AND ADOLESCENTS; COLLECTION OF ADDITIONAL IMMUNIZATION DATA.

(a) ACTIVITIES OF CENTERS FOR DISEASE CONTROL AND PREVENTION.—Section 317(j) of the Public Health Service Act (42 U.S.C. 247b(j)), as amended by section ___11, is further amended by adding at the end the following:

''(4)(A) For the purpose of carrying out activities to increase immunization rates for adults and adolescents through the immunization program under this subsection, and for the purpose of carrying out subsection (k)(2), there are authorized to be appropriated $50,000,000 for fiscal year 2003, and such sums as may be necessary for each of the fiscal years 2004 through 2006. Such authorization is in addition to amounts available under paragraphs (1), (2), and (3) for such purposes.

''(B) In expending amounts appropriated under subparagraph (A), the Secretary shall give priority to adults and adolescents who are medically underserved and are at risk for vaccine-preventable diseases, including as appropriate populations identified through projects under subsection (k)(2)(E).

''(C) The purposes for which amounts appropriated under subparagraph (A) are available include (with respect to immunizations for adults and adolescents) the payment of the costs of storing vaccines, outreach activities to inform individuals of the availability of the immunizations, and other program expenses necessary for the establishment or operation of immunization programs carried out or supported by States or other public entities pursuant to this subsection.

''(5) The Secretary shall annually submit to Congress a report that—

''(A) evaluates the extent to which the immunization system in the United States has been effective in providing for adequate immunization rates for adults and adolescents, taking into account the applicable year 2010 health objectives established by the Secretary regarding the health status of the people of the United States; and

''(B) describes any issues identified by the Secretary that may affect such rates.

''(6) In carrying out this subsection and paragraphs (1) and (2) of subsection (k), the Secretary shall consider recommendations regarding immunizations that are made in reports issued by the Institute of Medicine.''.

(b) RESEARCH, DEMONSTRATIONS, AND EDUCATION.—Section 317(k) of the Public Health Service Act (42 U.S.C. 247b(k)) is amended—

(1) by redesignating paragraphs (2) through (4) as paragraphs (3) through (5), respectively; and

(2) by inserting after paragraph (1) the following:

''(2) The Secretary, directly and through grants under paragraph (1), shall provide for a program of research, demonstration projects, and education in accordance with the following:

''(A) The Secretary shall coordinate with public and private entities (including nonprofit private entities), and develop and disseminate guidelines, toward the goal of ensuring that immunizations are routinely offered to adults and adolescents by public and private health care providers.

''(B) The Secretary shall cooperate with public and private entities to obtain information for the annual evaluations required in subsection (j)(5)(A).

''(C) The Secretary shall (relative to fiscal year 2001) increase the extent to which the Secretary collects data on the incidence, prevalence, and circumstances of diseases and adverse events that are experienced by adults and adolescents and may be associated with immunizations, including collecting data in cooperation with commercial laboratories.

''(D) The Secretary shall ensure that the entities with which the Secretary cooperates for purposes of subparagraphs (A) through (C) include managed care organizations, community-based organizations that provide health services, and other health care providers.

''(E) The Secretary shall provide for projects to identify racial and ethnic minority groups and other health disparity populations for which immunization rates for adults and adolescents are below such rates for the general population, and to determine the factors underlying such disparities.''.

SEC. ___13. IMMUNIZATION AWARENESS.

(a) DEVELOPMENT OF INFORMATION CONCERNING MENINGITIS.—

(1) IN GENERAL.—The Secretary of Health and Human Services, in consultation with the Director of the Centers for Disease Control and Prevention, shall develop and make available to entities described in paragraph (2) information concerning bacterial meningitis and the availability and effectiveness of vaccinations for populations targeted by the Advisory Committee on Immunization Practices (an advisory committee established by the Secretary of Health and Human Services, acting through the Centers for Disease Control and Prevention).

(2) ENTITIES.—An entity is described in this paragraph if the entity—

(A) is—

(i) a college or university; or

(ii) any other facility with a setting similar to a dormitory that houses age-appropriate populations for whom the Advisory Committee on Immunization Practices recommends such a vaccination; and

(B) is determined appropriate by the Secretary of Health and Human Services.

(b) DEVELOPMENT OF INFORMATION CONCERNING HEPATITIS.—

(1) IN GENERAL.—The Secretary of Health and Human Services, in consultation with the Director of the Centers for Disease Control and Prevention, shall develop and make available to entities described in paragraph (2) information concerning hepatitis A and B and the availability and effectiveness of vaccinations with respect to such diseases.

(2) ENTITIES.—An entity is described in this paragraph if the entity—

(A) is—

(i) a health care clinic that serves individuals diagnosed as being infected with HIV or as having other sexually transmitted diseases;

(ii) an organization or business that counsels individuals about international travel or who arranges for such travel;

(iii) a police, fire or emergency medical services organization that responds to natural or man-made disasters or emergencies;

(iv) a prison or other detention facility;

(v) a college or university; or

(vi) a public health authority or children's health service provider in areas of intermediate or high endemicity for hepatitis A as defined by the Centers for Disease Control and Prevention; and

(B) is determined appropriate by the Secretary of Health and Human Services.

SEC. ___14. SUPPLY OF VACCINES.

(a) IN GENERAL.—The Secretary of Health and Human Services, acting through the Director of the Centers for Disease Control and Prevention, shall prioritize, acquire, and maintain a supply of such prioritized vaccines sufficient to provide vaccinations throughout a 6-month period.

(b) PROCEEDS.—Any proceeds received by the Secretary of Health and Human Services from the sale of vaccines contained in the supply described in subsection (a), shall be available to the Secretary for the purpose of purchasing additional vaccines for the supply. Such proceeds shall remain available until expended.

(c) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated for the purpose of carrying out subsection (a) such sums as may be necessary for each of fiscal years 2003 through 2008.

Subtitle B—Vaccine Injury Compensation Program

SEC. ___21. ADMINISTRATIVE REVISION OF VACCINE INJURY TABLE.

Section 2114 of the Public Health Service Act (42 U.S.C. 300aa–14) is amended—

(1) in subsection (c), by striking paragraph (1) and inserting the following:

''(1) The Secretary may promulgate regulations to modify in accordance with paragraph (3) the Vaccine Injury Table. In promulgating such regulations, the Secretary shall provide for notice and for at least 60 days opportunity for public comment.''; and

(2) in subsection (d), by striking ''90 days'' and inserting ''60 days''.

SEC. ___22. EQUITABLE RELIEF.

Section 2111(a)(2)(A) of the Public Health Service Act (42 U.S.C. 300aa–11(a)(2)(A)) is amended by striking ''No person'' and all that follows through ''and—'' and inserting the following: ''No person may bring or maintain a civil action against a vaccine administrator or manufacturer in a State or Federal court for damages arising from, or equitable relief relating to, a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988 and no such court may award damages or equitable relief for any such vaccine-related injury or death, unless the person proves past or present physical injury and a timely petition has been filed, in accordance with section 2116 for compensation under the Program for such injury or death and—''.

SEC. ___23. PARENT OR OTHER THIRD PARTY PETITIONS FOR COMPENSATION.

(a) LIMITATIONS ON DERIVATIVE PETITIONS.—Section 2111(a)(2) of the Public Health Service Act (42 U.S.C. 300aa–11(a)(2)) is amended—

(1) in subparagraph (B), by inserting ''or (B)'' after ''subparagraph (A)'';

(2) by redesignating subparagraph (B) as subparagraph (C); and

(3) by inserting after subparagraph (A) the following:

''(B)(i) No parent, legal guardian, or spouse (referred to in this title as a parent or other third party) may bring or maintain a civil action against a vaccine administrator or manufacturer in a Federal or State court for damages or equitable relief relating to a vaccine-related injury or death, including damages for loss of consortium, society, companionship, or services, loss of earnings, medical or other expenses, and emotional distress, and no court may award damages or equitable relief in such an action, unless—

''(I) the person who sustained the underlying vaccine-related injury or death upon which such parent's or other third party's claim is premised has, in accordance with section 2112, been awarded compensation in a final judgment of the United States Court of Federal Claims and such judgment is subject to no further appeal or review;

''(II) such parent or other third party timely filed a derivative petition, in accordance with section 2116; and

''(III)(aa) the United States Court of Federal Claims has issued judgment under section 2112 on the derivative petition, and such parent or other third party elects under section 2121(a) to file a civil action; or

''(bb) such parent or other third party elects to withdraw such derivative petition under section 2121(b) or such petition is considered withdrawn under such section.

''(ii) Any civil action brought in accordance with this subparagraph shall be subject to the standards and procedures set forth in sections 2122 and 2123, regardless of whether the action arises directly from a vaccine-related injury or death associated with the administration of a vaccine. In a case in which the person who sustained the underlying vaccine-related injury or death upon which such parent's or other third party's civil action is premised elects under section 2121(a) to receive the compensation awarded, such parent or other third party may not bring a civil action for damages or equitable relief, and no court may award damages or equitable relief, for any injury or loss of the type set forth in section 2115(a) or that might in any way overlap with or otherwise duplicate compensation of the type available under section 2115(a).''.

(b) ELIGIBLE PERSONS.—Section 2111(a)(9) of the Public Health Service Act (42 U.S.C. 300aa–11(a)(9)) is amended by striking the period and inserting ''and to a parent or other third party to the extent such parent or other third party seeks damages or equitable relief relating to a vaccine-related injury or death sustained by a person who is qualified to file a petition for compensation under the Program.''.

(c) PETITIONERS.—Section 2111(b) of the Public Health Service Act (42 U.S.C. 300aa–11(b)) is amended—

(1) in paragraph (1)—

(A) in subparagraph (A), by striking ''(B)'' and inserting ''(C)'';

(B) by redesignating subparagraph (B) as subparagraph (C); and

(C) by inserting after subparagraph (A) the following:

''(B) Except as provided in subparagraph (C), any parent or other third party with respect to a person—

''(i) who has sustained a vaccine-related injury or death;

''(ii) who has filed a petition for compensation under the Program (or whose legal representative has filed such a petition as authorized in subparagraph (A)); and

''(iii) who has, in accordance with section 2112, been awarded compensation in a final judgment of the United States Court of Federal Claims that is subject to no further appeal or review;

may, if such parent or other third party meets the requirements of subsection (d), file a derivative petition under this section.''; and

(2) in paragraph (2)—

(A) by inserting ''by or on behalf of the person who sustained the vaccine-related injury or death'' after ''filed''; and

(B) by adding at the end the following: ''A parent or other third party may file only 1 derivative petition with respect to each administration of a vaccine.''.

(d) DERIVATIVE PETITION CONTENTS.—Section 2111 of the Public Health Service Act (42 U.S.C. 300aa–11) is amended—

(1) by redesignating subsections (d) and (e) as subsections (e) and (f), respectively; and

(2) by inserting after subsection (c) the following:

''(d) DERIVATIVE PETITIONS.—

''(1) If the parent or other third party with respect to the person who sustained the vaccine-related injury or death seeks compensation under the Program, such parent or other third party shall file a timely derivative petition for compensation under the Program in accordance with this section.

''(2) Such a derivative petition shall contain—

''(A) except for records that are unavailable as described in subsection (c)(3), an affidavit, and supporting documentation, demonstrating that—

''(i) such person was, in accordance with section 2112, previously awarded compensation for the underlying vaccine-related injury or death upon which such parent's or other third party's derivative petition is premised in a final judgment of the United States Court of Federal Claims and such judgment is subject to no further appeal or review;

''(ii) the derivative petition was filed not later than 60 days after the date on which such judgment became final and subject to no further appeal or review;

''(iii) such parent or other third party suffered a loss compensable under section 2115(b) as a result of the vaccine-related injury or death sustained by such person; and

''(iv) such parent or other third party has not previously collected an award or settlement of a civil action for damages for such loss; and

''(B) records establishing such parent's or other third party's relationship to the person who sustained the vaccine-related injury or death.''.

(e) DETERMINATION OF ELIGIBILITY FOR COMPENSATION.—Section 2113(a)(1) of the Public Health Service Act (42 U.S.C. 300aa–13(a)(1)) is amended—

(1) in subparagraph (A), by inserting ''or, as applicable, section 2111(d)'' before the comma; and

(2) in subparagraph (B), by inserting ''or, as applicable, that the injury or loss described in the derivative petition is due to factors unrelated to the vaccine-related injury or death'' after ''the petition''.

(f) COMPENSATION.—Section 2115 of the Public Health Service Act (42 U.S.C. 300aa–15) is amended—

(1) by redesignating subsections (b) through (j) as subsections (c) through (k), respectively;

(2) by inserting after subsection (a) the following:

''(b) DERIVATIVE PETITIONS.—Compensation awarded under the Program to a parent or other third party who files a derivative petition under section 2111 for a loss sustained as a result of a vaccine-related injury or death sustained by the injured party shall include compensation, if any, for loss of consortium, society, companionship, or services, in an amount not to exceed the lesser of $250,000 or the total amount of compensation awarded to the person who sustained the underlying vaccine-related injury or death.'';

(3) in subsection (e)(2), as so redesignated by paragraph (1)—

(A) by striking ''(2) and (3)'' and inserting ''(2), (3), and (4)''; and

(B) by inserting ''and subsection (b),'' after ''(a),'';

(4) in subsection (g), as so redesignated by paragraph (1), in paragraph (4)(B), by striking ''subsection (j)'' and inserting ''subsection (k)'';

(5) in subsection (j), as so redesignated by paragraph (1)—

(A) in paragraph (1), by striking ''subsection (j)'' and inserting ''subsection (k)''; and

(B) in paragraph (2), by inserting '', or to a parent or other third party with respect to a person who sustained a vaccine-related injury or death,'' after ''death''; and

(6) in subsection (k), as so redesignated by paragraph (1), by striking ''subsection (f)(4)(B)'' and inserting ''subsection (g)(4)(B)''.

SEC. ___24. JURISDICTION TO DISMISS ACTIONS IMPROPERLY BROUGHT.

Section 2111(a)(3) of the Public Health Service Act (42 U.S.C. 300aa–11(a)(3)) is amended by adding at the end the following: ''If any civil action which is barred under subparagraph (A) or (B) of paragraph (2) is filed or maintained in a State court, or any vaccine administrator or manufacturer is made a party to any civil action brought in State court (other than a civil action which may be brought under paragraph (2)) for damages or equitable relief for a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, the civil action may be removed by the defendant or defendants to the United States

Court of Federal Claims, which shall have jurisdiction over such civil action, and which shall dismiss such action. The notice required by section 1446 of title 28, United States Code, shall be filed with the United States Court of Federal Claims, and that court shall proceed in accordance with sections 1446 through 1451 of title 28, United States Code.''.

SEC. ___25. APPLICATION.

Section 2111(a)(9) of the Public Health Service Act (42 U.S.C. 300aa–11(a)(9)) is amended by striking ''This'' and inserting ''Except as provided in paragraph (2), this''.

SEC. ___26. CLARIFICATION OF WHEN INJURY IS CAUSED BY FACTOR UNRELATED TO ADMINISTRATION OF VACCINE.

Section 2113(a)(2)(B) of the Public Health Service Act (42 U.S.C. 300aa–13(a)(2)(B)) is amended—

(1) by inserting ''structural lesions, genetic disorders,'' after ''and related anoxia),'';

(2) by inserting ''(without regard to whether the cause of the infection, toxin, trauma, structural lesion, genetic disorder, or metabolic disturbance is known)'' after ''metabolic disturbances''; and

(3) by striking ''but'' and inserting ''and''.

SEC. ___27. INCREASE IN AWARD IN THE CASE OF A VACCINE-RELATED DEATH AND FOR PAIN AND SUFFERING.

Section 2115(a) of the Public Health Service Act (42 U.S.C. 300aa–15(a)) is amended—

(1) in paragraph (2), by striking ''$250,000'' and inserting ''$350,000''; and

(2) in paragraph (4), by striking ''$250,000'' and inserting ''$350,000''.

SEC. ___28. BASIS FOR CALCULATING PROJECTED LOST EARNINGS.

Section 2115(a)(3)(B) of the Public Health Service Act (42 U.S.C. 300aa–15(a)(3)(B)) is amended by striking ''loss of earnings'' and all that follows and inserting the following: ''loss of earnings determined on the basis of the annual estimate of the average (mean) gross weekly earnings of wage and salary workers age 18 and over (excluding the incorporated self-employed) in the private nonfarm sector (which includes all industries other than agricultural production crops and livestock), as calculated annually by the Bureau of Labor Statistics from the quarter sample data of the Current Population Survey, or as calculated by such similar method as the Secretary may prescribe by regulation, less appropriate taxes and the average cost of a health insurance policy, as determined by the Secretary.''.

SEC. ___29. ALLOWING COMPENSATION FOR FAMILY COUNSELING EXPENSES AND EXPENSES OF ESTABLISHING GUARDIANSHIP.

(a) FAMILY COUNSELING EXPENSES IN POST-1988 CASES.—Section 2115(a) of the Public Health Service Act (42 U.S.C. 300aa–15(a)) is amended by adding at the end to following:

''(5) Actual unreimbursable expenses that have been or will be incurred for family counseling as is determined to be reasonably necessary and that result from the vaccine-related injury from which the petitioner seeks compensation.''.

(b) EXPENSES OF ESTABLISHING GUARDIANSHIPS IN POST-1988 CASES.—Section 2115(a) of the Public Health Service Act (42 U.S.C. 300aa–15(a)), as amended by subsection (a), is further amended by adding at the end the following:

''(6) Actual unreimbursable expenses that have been, or will be reasonably incurred to establish and maintain a guardianship or conservatorship for an individual who has suffered a vaccine-related injury, including attorney fees and other costs incurred in a proceeding to establish and maintain such guardianship or conservatorship.''.

(c) CONFORMING AMENDMENT FOR CASES FROM 1988 AND EARLIER.—Section 2115 of the Public Health Service Act (42 U.S.C. 300aa–15) is amended in subsection (c), as so redesignated by section ___23(f)—

(1) in paragraph (2), by striking ''and'' at the end;

(2) in paragraph (3), by striking ''(e)'' and inserting ''(f))'';

(3) by redesignating paragraph (3) as paragraph (5); and

(4) by inserting after paragraph (2), the following:

''(3) family counseling expenses (as provided for in paragraph (5) of subsection (a));

''(4) expenses of establishing guardianships (as provided for in paragraph (6) of subsection (a)); and''.

SEC. ___30. ALLOWING PAYMENT OF INTERIM COSTS.

Section 2115 of the Public Health Service Act (42 U.S.C. 300aa–15) is amended in subsection (f), as so redesignated by section ___23(f), by adding at the end the following:

''(4) A special master or court may make an interim award of costs if—

''(A) the case involves a vaccine administered on or after October 1, 1988;

''(B) the special master or court has determined whether or not the petitioner is entitled to compensation under the Program;

''(C) the award is limited to other costs (within the meaning of paragraph (1)(B)) incurred in the proceeding; and

''(D) the petitioner provides documentation verifying the expenditure of the amount for which compensation is sought.''.

SEC. ___31. PROCEDURE FOR PAYING ATTORNEYS' FEES.

Section 2115 of the Public Health Service Act (42 U.S.C. 300aa–15), is amended in subsection (f), as so redesignated by section ___23(f) and amended by section ___30, by adding at the end the following:

''(5) When a special master or court awards attorney fees or costs under paragraph (1) or (4), it may order that such fees or costs be payable solely to the petitioner's attorney if—

''(A) the petitioner expressly consents; or

''(B) the special master or court determines, after affording to the Secretary and to all interested persons the opportunity to submit relevant information, that—

''(i) the petitioner cannot be located or refuses to respond to a request by the special master or court for information, and there is no practical alternative means to ensure that the attorney will be reimbursed for such fees or costs expeditiously; or

''(ii) there are otherwise exceptional circumstances and good cause for paying such fees or costs solely to the petitioner's attorney.''.

SEC. ___32. EXTENSION OF STATUTE OF LIMITATIONS.

(a) GENERAL RULE.—Section 2116(a) of the Public Health Service Act (42 U.S.C. 300aa–16(a)) is amended—

(1) in paragraph (2) by striking ''36 months'' and inserting ''6 years''; and

(2) in paragraph (3), by striking ''48 months'' and inserting ''6 years''.

(b) CLAIMS BASED ON REVISIONS TO TABLE.—Section 2116 of the Public Health Service Act (42 U.S.C. 300aa–16) is amended by striking subsection (b) and inserting the following:

''(b) EFFECT OF REVISED TABLE.—If at any time the Vaccine Injury Table is revised and the effect of such revision is to make an individual eligible for compensation under the program, where, before such revision, such individual was not eligible for compensation under the program, or to significantly increase the likelihood that an individual will be able to obtain compensation under the program, such person may, and shall before filing a civil action for equitable relief or monetary damages, notwithstanding section 2111(b)(2), file a petition for such compensation if—

''(1) the vaccine-related death or injury with respect to which the petition is filed occurred not more than 8 years before the effective date of the revision of the table; and

''(2) either—

''(A) the petition satisfies the conditions described in subsection (a); or

''(B) the date of the occurrence of the first symptom or manifestation of onset of the injury occurred more than 4 years before the petition is filed, and the petition is filed not more than 2 years after the effective date of the revision of the table.''.

(c) DERIVATIVE PETITIONS.—Section 2116 of the Public Health Service Act (42 U.S.C. 300aa–16) is amended by adding at the end the following:

''(d) DERIVATIVE PETITIONS.—No derivative petition may be filed for compensation under the Program later than 60 days after the date on which the United States Court of Federal Claims has entered final judgment and the time for all further appeal or review has expired on the underlying claim of the person who sustained the vaccine-related injury or death upon which the derivative petition is premised.''.

(d) TIMELY RESOLUTIONS OF CLAIMS.—

(1) SPECIAL MASTER DECISION.—Section 2112(d)(3)(A) of the Public Health Service Act (42 U.S.C. 300aa–12(d)(3)(A)) is amended by adding at the end the following: ''For purposes of this subparagraph, the petition shall be deemed to be filed on the date on which all petition contents and supporting documents required under section 2111(c) and, when applicable, section 2111(d) and the Vaccine Rules of the United States Court of Federal Claims, such as an affidavit and supporting documentation, are served on the Secretary and filed with the clerk of the United States Court of Federal Claims.''.

(2) COURT OF FEDERAL CLAIMS DECISION.—Section 2121(b) of the Public Health Service Act (42 U.S.C. 300aa–21(b)) is amended by adding at the end the following: ''For purposes of this subsection, the petition shall be deemed to be filed on the date on which all petition contents and supporting documents required under section 2111(c) and, when applicable, section 2111(d) and the Vaccine Rules of the United States Court of Federal Claims, such as an affidavit and supporting documentation, are served on the Secretary and filed with the clerk of the United States Court of Federal Claims.''.

SEC. ___33. ADVISORY COMMISSION ON CHILDHOOD VACCINES.

(a) SELECTION OF PERSONS INJURED BY VACCINES AS PUBLIC MEMBERS.—Section 2119(a)(1)(B) of the Public Health Service Act (42 U.S.C. 300aa–19(a)(1)(B)) is amended by striking ''of whom'' and all that follows and inserting the following: ''of whom 1 shall be the legal representative of a child who has suffered a vaccine-related injury or death, and at least 1 other shall be either the legal representative of a child who has suffered a vaccine-related injury or death or an individual who has personally suffered a vaccine-related injury.''.

(b) MANDATORY MEETING SCHEDULE ELIMINATED.—Section 2119(c) of the Public Health Service Act (42 U.S.C. 300aa–19(c)) is amended by striking ''not less often than four times per year and''.

SEC. ___34. CLARIFICATION OF STANDARDS OF RESPONSIBILITY.

(a) GENERAL RULE.—Section 2122(a) of the Public Health Service Act (42 U.S.C. 300aa–22(a)) is amended by striking ''and (e) State law shall apply to a civil action brought for damages'' and inserting ''(d), and (f) State law shall apply to a civil action brought for damages or equitable relief''; and

(b) UNAVOIDABLE ADVERSE SIDE EFFECTS.—Section 2122(b)(1) of the Public Health Service Act (42 U.S.C. 300aa–22(b)(1)) is amended by inserting ''or equitable relief'' after ''for damages''.

(c) DIRECT WARNINGS.—Section 2122(c) of the Public Health Service Act (42 U.S.C. 300aa–22(c)) is amended by inserting ''or equitable relief'' after ''for damages''.

(d) CONSTRUCTION.—Section 2122(d) of the Public Health Service Act (42 U.S.C. 300aa–22(d)) is amended—

(1) by inserting ''or equitable relief'' after ''for damages''; and

(2) by inserting ''or relief'' after ''which damages''.

(e) PAST OR PRESENT PHYSICAL INJURY.—Section 2122 of the Public Health Service Act (42 U.S.C. 300aa–22) is amended—

(1) by redesignating subsections (d) and (e) as subsections (e) and (f), respectively; and

(2) by inserting after subsection (c) the following:

''(d) PAST OR PRESENT PHYSICAL INJURY.—No vaccine manufacturer or vaccine administrator shall be liable in a civil action brought after October 1, 1988, for equitable or monetary relief absent proof of past or present physical injury from the administration of a vaccine, nor shall any vaccine manufacturer or vaccine administrator be liable in any such civil action for claims of medical monitoring, or increased risk of harm.''.

SEC. ___35. CLARIFICATION OF DEFINITION OF MANUFACTURER.

Section 2133(3) of the Public Health Service Act (42 U.S.C. 300aa–33(3)) is amended—

(1) in the first sentence, by striking ''under its label any vaccine set forth in the Vaccine Injury Table'' and inserting ''any vaccine set forth in the Vaccine Injury table, including any component or ingredient of any such vaccine''; and

(2) in the second sentence, by inserting ''including any component or ingredient of any such vaccine'' before the period.

SEC. ___36. CLARIFICATION OF DEFINITION OF VACCINE-RELATED INJURY OR DEATH.

Section 2133(5) of the Public Health Service Act (42 U.S.C. 300aa–33(5)) is amended by adding at the end the following: ''For purposes of the preceding sentence, an adulterant or contaminant shall not include any component or ingredient listed in a vaccine's product license application or product label.''.

SEC. ___37. CLARIFICATION OF DEFINITION OF VACCINE.

Section 2133 of the Public Health Service Act (42 U.S.C. 300aa–33) is amended by adding at the end the following:

''(7) The term 'vaccine' means any preparation or suspension, including a preparation or suspension containing an attenuated or inactive microorganism or subunit thereof or toxin, developed or administered to produce or enhance the body's immune response to a disease or diseases and includes all components and ingredients listed in the vaccines's product license application and product label.''.

SEC. ___38. AMENDMENTS TO VACCINE INJURY COMPENSATION TRUST FUND.

(a) EXPANSION OF COMPENSATED LOSS.—Section 9510(c)(1)(A) of the Internal Revenue Code of 1986 is amended by inserting '', or related loss,'' after ''death''.

(b) INCREASE IN LIMIT ON ADMINISTRATIVE EXPENSES.—Subparagraph (B) of section 9510(c)(1) of the Internal Revenue Code of 1986 is amended—

(1) by striking ''(but not in excess of the base amount of $9,500,000 for any fiscal year)''; and

(2) by striking the period and inserting '', provided that such administrative costs shall not exceed the greater of—

''(i) the base amount of $9,500,000,

''(ii) 125 percent of the base amount for any fiscal year in which the total number of claims pending under such subtitle exceeds 150 percent of the average number of claims pending in the preceding 5 years,

''(iii) 175 percent of the base amount for any fiscal year in which the total number of claims pending under such subtitle exceeds 200 percent of the average number of claims pending in the preceding 5 years,

''(iv) 225 percent of the base amount for any fiscal year in which the total number of claims pending under such subtitle exceeds 250 percent of the average number of claims pending in the preceding 5 years, or

''(v) 275 percent of the base amount for any fiscal year in which the total number of claims pending under such subtitle exceeds 300 percent of the average number of claims pending in the preceding 5 years.''.

(c) CONFORMING AMENDMENT.—Section 9510(c)(1)(A) of the Internal Revenue Code of 1986 is amended by striking ''October 18, 2000'' and inserting ''the date of enactment of the Improved Vaccine Affordability and Availability Act''.

SEC. ___39. ONGOING REVIEW OF CHILDHOOD VACCINE DATA.

Part C of title XXI of the Public Health Service Act (42 U.S.C. 300a–25 et seq.) is amended by adding at the end the following:

''SEC. 2129. ONGOING REVIEW OF CHILDHOOD VACCINE DATA.

''(a) IN GENERAL.—Not later than 6 months after the date of enactment of this section, the Secretary shall enter into a contract with the Institute of Medicine of the National Academy of Science under which the Institute shall conduct an ongoing, comprehensive review of new scientific data on childhood vaccines (according to priorities agreed upon from time to time by the Secretary and the Institute of Medicine).

''(b) REPORTS.—Not later than 3 years after the date on which the contract is entered into under subsection (a), the Institute of Medicine shall submit to the Secretary a report on the findings of studies conducted, including findings as to any adverse events associated with childhood vaccines, including conclusions concerning causation of adverse events by such vaccines, and other appropriate recommendations, based on such findings and conclusions.

''(c) FAILURE TO ENTER INTO CONTRACT.—If the Secretary and the Institute of Medicine are unable to enter into the contract described in subsection (a), the Secretary shall enter into a contract with another qualified nongovernmental scientific organization for the purposes described in subsections (a) and (b).

''(d) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated such sums as may be necessary for each of fiscal years 2003, 2004, 2005 and 2006.''.

SEC. ___40. PENDING ACTIONS.

The amendments made by this title shall apply to all actions or proceedings pending on or after the date of enactment of this Act, unless a court of competent jurisdiction has entered judgment (regardless of whether the time for appeal has expired) in such action or proceeding disposing of the entire action or proceeding.

SEC. ___41. REPORT.

Not later than 1 year after the date of enactment of this Act, and annually thereafter, the Advisory Commission on Childhood Vaccines shall report to the Secretary of Health and Human Services regarding the status of the Vaccine Injury Compensation Trust Fund, and shall make recommendations to the Secretary regarding the allocation of funds from the Vaccine Injury Compensation Trust Fund.

SA 4345. Mr. GRAHAM (for himself, Mr. SMITH of Oregon, Mr. MILLER, Mrs. LINCOLN, Mr. BINGAMAN, Mr. KENNEDY, and Ms. STABENOW) proposed an amendment to amendment SA 4299 proposed by Mr. REID (for Mr. DORGAN (for himself, Mr. WELLSTONE, Mr. JEFFORDS, Ms. STABENOW, Ms. COLLINS, Mr. LEVIN, Mr. JOHNSON, Mr. MILLER, Mr. DURBIN, Mr. FEINGOLD, and Mr. HARKIN)) to the bill (S. 812) to amend the Federal Food, Drug, and Cosmetic Act to provide greater access to affordable pharmaceuticals; as follows:

At the end, add the following:

TITLE II—MEDICARE OUTPATIENT PRESCRIPTION DRUG BENEFIT PROGRAM

SEC. 201. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This title may be cited as the ''Medicare Prescription Drug Cost Protection Act of 2002''.

(b) TABLE OF CONTENTS.—The table of contents of this title is as follows:

SEC. 202. MEDICARE OUTPATIENT PRESCRIPTION DRUG BENEFIT PROGRAM.

(a) ESTABLISHMENT.—Title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) is amended by redesignating part D as part E and by inserting after part C the following new part:

''PART D—OUTPATIENT PRESCRIPTION DRUG BENEFIT PROGRAM

''DEFINITIONS

''SEC. 1860. In this part:

''(1) COVERED OUTPATIENT DRUG.—

''(A) IN GENERAL.—Except as provided in subparagraph (B), the term 'covered outpatient drug' means any of the following products:

''(i) A drug which may be dispensed only upon prescription, and—

''(I) which is approved for safety and effectiveness as a prescription drug under section 505 of the Federal Food, Drug, and Cosmetic Act;

''(II)(aa) which was commercially used or sold in the United States before the date of enactment of the Drug Amendments of 1962 or which is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a drug, and (bb) which has not been the subject of a final determination by the Secretary that it is a 'new drug' (within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act) or an action brought by the Secretary under section 301, 302(a), or 304(a) of such Act to enforce section 502(f) or 505(a) of such Act; or

''(III)(aa) which is described in section 107(c)(3) of the Drug Amendments of 1962 and for which the Secretary has determined there is a compelling justification for its medical need, or is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a drug, and (bb) for which the Secretary has not issued a notice of an opportunity for a hearing under section 505(e) of the Federal Food, Drug, and Cosmetic Act on a proposed order of the Secretary to withdraw approval of an application for such drug under such section because the Secretary has determined that the drug is less than effective for all conditions of use prescribed, recommended, or suggested in its labeling.

''(ii) A biological product which—

''(I) may only be dispensed upon prescription;

''(II) is licensed under section 351 of the Public Health Service Act; and

''(III) is produced at an establishment licensed under such section to produce such product.

''(iii) Insulin approved under appropriate Federal law, including needles and syringes for the administration of such insulin.

''(iv) A prescribed drug or biological product that would meet the requirements of clause (i) or (ii) except that it is available over-the-counter in addition to being available upon prescription.

''(B) EXCLUSION.—The term 'covered outpatient drug' does not include any product—

''(i) except as provided in subparagraph (A)(iv), which may be distributed to individuals without a prescription;

''(ii) for which payment is available under part A or B or would be available under part B but for the application of a deductible under such part (unless payment for such product is not available because benefits under part A or B have been exhausted), determined, except as provided in subparagraph (C), without regard to whether the beneficiary involved is entitled to benefits under part A or enrolled under part B; or

''(iii) except for agents used to promote smoking cessation and agents used for the treatment of obesity, for which coverage may be excluded or restricted under section 1927(d)(2).

''(C) CLARIFICATION REGARDING IMMUNOSUPPRESSIVE DRUGS.—In the case of a beneficiary who is not eligible for any coverage under part B of drugs described in section 1861(s)(2)(J) because of the requirements under such section (and would not be so eligible if the individual were enrolled under such part), the term 'covered outpatient drug' shall include such drugs if the drugs would otherwise be described in subparagraph (A).

''(2) ELIGIBLE BENEFICIARY.—The term 'eligible beneficiary' means an individual that is entitled to benefits under part A or enrolled under part B.

''(3) ELIGIBLE ENTITY.—The term 'eligible entity' means any entity that the Secretary determines to be appropriate to provide eligible beneficiaries with covered outpatient drugs under a plan under this part, including—

''(A) a pharmacy benefit management company;

''(B) a retail pharmacy delivery system;

''(C) a health plan or insurer;

''(D) a State (through mechanisms established under a State plan under title XIX);

''(E) any other entity approved by the Secretary; or

''(F) any combination of the entities described in subparagraphs (A) through (E) if the Secretary determines that such combination—

''(i) increases the scope or efficiency of the provision of benefits under this part; and

''(ii) is not anticompetitive.

''(4) MEDICARE+CHOICE ORGANIZATION; MEDICARE+CHOICE PLAN.—The terms 'Medicare+Choice organization' and 'Medicare+Choice plan' have the meanings given such terms in subsections (a)(1) and (b)(1), respectively, of section 1859 (relating to definitions relating to Medicare+Choice organizations).

''(5) PRESCRIPTION DRUG ACCOUNT.—The term 'Prescription Drug Account' means the Prescription Drug Account (as established under section 1860K) in the Federal Supplementary Medical Insurance Trust Fund under section 1841.

''ESTABLISHMENT OF OUTPATIENT PRESCRIPTION DRUG BENEFIT PROGRAM

''SEC. 1860A. (a) PROVISION OF BENEFIT.—

''(1) IN GENERAL.—Beginning in 2005, the Secretary shall provide for and administer an outpatient prescription drug benefit program under which each eligible beneficiary enrolled under this part shall be provided with coverage of covered outpatient drugs as follows:

''(A) MEDICARE+CHOICE PLAN.—If the eligible beneficiary is eligible to enroll in a Medicare+Choice plan, the beneficiary—

''(i) may enroll in such a plan; and

''(ii) if so enrolled, shall obtain coverage of covered outpatient drugs through such plan.

''(B) MEDICARE PRESCRIPTION DRUG PLAN.—If the eligible beneficiary is not enrolled in a Medicare+Choice plan, the beneficiary shall obtain coverage of covered outpatient drugs through enrollment in a plan offered by an eligible entity with a contract under this part.

''(2) VOLUNTARY NATURE OF PROGRAM.—Nothing in this part shall be construed as requiring an eligible beneficiary to enroll in the program established under this part.

''(3) SCOPE OF BENEFITS.—The program established under this part shall provide for coverage of all therapeutic categories and classes of covered outpatient drugs.

''(b) FINANCING.—The costs of providing benefits under this part shall be payable from the Prescription Drug Account.

''ENROLLMENT UNDER PROGRAM

''SEC. 1860B. (a) ESTABLISHMENT OF PROCESS.—

''(1) IN GENERAL.—The Secretary shall establish a process through which an eligible beneficiary (including an eligible beneficiary enrolled in a Medicare+Choice plan offered by a Medicare+Choice organization) may make an election at any time to enroll under the program under this part.

''(2) ENROLLMENT AND REENROLLMENT AT ANY TIME.—Under the process established under paragraph (1), an eligible beneficiary, beginning January 1, 2005, may—

''(A) make an election to enroll under the program under this part at any time; and

''(B) terminate such election at any time and reenroll under such program at any time.

''(3) OPEN ENROLLMENT PERIOD PRIOR TO JANUARY 1, 2005, FOR INDIVIDUALS CURRENTLY ELIGIBLE.—The Secretary shall establish an open enrollment period of not less than 5 months to ensure that—

''(A) an individual who meets or will meet the definition of an eligible beneficiary under section 1860(2) as of January 1, 2005, is permitted to enroll under the program under this part prior to such date; and

''(B) coverage under this part for such an individual is effective as of such date.

''(4) REQUIREMENT OF ENROLLMENT.—An eligible beneficiary must be enrolled under this part in order to be eligible to receive coverage of covered outpatient drugs under this title.

''(5) LIMITATION.—Coverage under this part shall not begin prior to January 1, 2005.

''(b) TERMINATION.—

''(1) IN GENERAL.—The causes of termination specified in section 1838 shall apply to this part in a similar manner as such causes apply to part B.

''(2) COVERAGE TERMINATED BY TERMINATION OF COVERAGE UNDER PARTS A AND B.—

''(A) IN GENERAL.—In addition to the causes of termination specified in paragraph (1), the Secretary shall terminate an individual's coverage under this part if the individual is no longer enrolled in either part A or B.

''(B) EFFECTIVE DATE.—The termination described in subparagraph (A) shall be effective on the effective date of termination of coverage under part A or (if later) under part B.

''(3) PROCEDURES REGARDING TERMINATION OF A BENEFICIARY UNDER A PLAN.—The Secretary shall establish procedures for determining the status of an eligible beneficiary's enrollment under this part if the beneficiary's enrollment in a plan offered by an eligible entity under this part is terminated by the entity for cause (pursuant to procedures established by the Secretary under section 1860C(a)(1)).

''ENROLLMENT IN A PLAN

''SEC. 1860C. (a) PROCESS.—

''(1) ESTABLISHMENT.—

''(A) ELECTION.—

''(i) IN GENERAL.—The Secretary shall establish a process through which an eligible beneficiary who is enrolled under this part but not enrolled in a Medicare+Choice plan offered by a Medicare+Choice organization—

''(I) shall make an annual election to enroll in any plan offered by an eligible entity that has been awarded a contract under this part and serves the geographic area in which the beneficiary resides; and

''(II) may make an annual election to change the election under this clause.

''(ii) DEFAULT ENROLLMENT.—Such process shall include for the default enrollment in such a plan in the case of an eligible beneficiary who is enrolled under this part but who has failed to make an election of such a plan.

''(B) RULES.—In establishing the process under subparagraph (A), the Secretary shall—

''(i) use rules similar to the rules for enrollment, disenrollment, and termination of enrollment with a Medicare+Choice plan under section 1851, including—

''(I) the establishment of special election periods under subsection (e)(4) of such section; and

''(II) the application of the guaranteed issue and renewal provisions of subsection (g) of such section (other than paragraph (3)(C)(i), relating to default enrollment); and

''(ii) coordinate enrollments, disenrollments, and terminations of enrollment under part C with enrollments,

disenrollments, and terminations of enrollment under this part.

''(2) FIRST ENROLLMENT PERIOD FOR PLAN ENROLLMENT FOR INDIVIDUALS CURRENTLY ELIGIBLE.—The process developed under paragraph (1) shall—

''(A) ensure—

''(i) that an individual who meets or will meet the definition of an eligible beneficiary under section 1860(2) as of January 1, 2005, is permitted to enroll with an eligible entity prior to January 1, 2005; and

''(ii) that coverage under this part for such an individual is effective as of such date; and

''(B) be coordinated with the open enrollment described in section 1860B(a)(3).

''(b) MEDICARE+CHOICE ENROLLEES.—

''(1) IN GENERAL.—An eligible beneficiary who is enrolled under this part and enrolled in a Medicare+Choice plan offered by a Medicare+Choice organization shall receive coverage of covered outpatient drugs under this part through such plan.

''(2) RULES.—Enrollment in a Medicare+Choice plan is subject to the rules for enrollment in such a plan under section 1851.

''PROVIDING INFORMATION TO BENEFICIARIES

''SEC. 1860D. (a) ACTIVITIES.—

''(1) IN GENERAL.—The Secretary shall conduct activities that are designed to broadly disseminate information to eligible beneficiaries (and prospective eligible beneficiaries) regarding the coverage provided under this part.

''(2) SPECIAL RULE FOR FIRST ENROLLMENT UNDER THE PROGRAM.—To the extent practicable, the activities described in paragraph (1) shall ensure that individuals who meet or will meet the definition of an eligible beneficiary under section 1860(2) as of January 1, 2005, and other prospective eligible beneficiaries, are provided with such information at least 30 days prior to the open enrollment period described in section 1860B(a)(3).

''(b) REQUIREMENTS.—

''(1) IN GENERAL.—The activities described in subsection (a) shall—

''(A) be similar to the activities performed by the Secretary under section 1851(d);

''(B) be coordinated with the activities performed by the Secretary under such section and under section 1804; and

''(C) provide for the dissemination of information comparing the plans offered by eligible entities under this part that are available to eligible beneficiaries residing in an area.

''(2) COMPARATIVE INFORMATION.—The comparative information described in paragraph (1)(C) shall include a comparison of the following:

''(A) BENEFITS.—The benefits provided under the plan, including the negotiated prices beneficiaries will be charged for covered outpatient drugs, any preferred pharmacy networks used by the eligible entity under the plan, and the formularies and appeals processes under the plan.

''(B) QUALITY AND PERFORMANCE.—To the extent available, the quality and performance of the eligible entity offering the plan.

''(C) BENEFICIARY COST-SHARING.—The cost-sharing required of eligible beneficiaries under the plan.

''(D) CONSUMER SATISFACTION SURVEYS.—To the extent available, the results of consumer satisfaction surveys regarding the plan and the eligible entity offering such plan.

''(E) ADDITIONAL INFORMATION.—Such additional information as the Secretary may prescribe.

''(3) INFORMATION STANDARDS.—The Secretary shall develop standards to ensure that the information provided to eligible beneficiaries under this part is complete, accurate, and uniform.

''(c) USE OF MEDICARE CONSUMER COALITIONS TO PROVIDE INFORMATION.—

''(1) IN GENERAL.—The Secretary may contract with Medicare Consumer Coalitions to conduct the informational activities under—

''(A) this section;

''(B) section 1851(d); and

''(C) section 1804.

''(2) SELECTION OF COALITIONS.—If the Secretary determines the use of Medicare Consumer Coalitions to be appropriate, the Secretary shall—

''(A) develop and disseminate, in such areas as the Secretary determines appropriate, a request for proposals for Medicare Consumer Coalitions to contract with the Secretary in order to conduct any of the informational activities described in paragraph (1); and

''(B) select a proposal of a Medicare Consumer Coalition to conduct the informational activities in each such area, with a preference for broad participation by organizations with experience in providing information to beneficiaries under this title.

''(3) PAYMENT TO MEDICARE CONSUMER COALITIONS.—The Secretary shall make payments to Medicare Consumer Coalitions contracting under this subsection in such amounts and in such manner as the Secretary determines appropriate.

''(4) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to the Secretary, out of any moneys in the Treasury not otherwise appropriated, such sums as may be necessary to contract with Medicare Consumer Coalitions under this section.

''(5) MEDICARE CONSUMER COALITION DEFINED.—In this subsection, the term 'Medicare Consumer Coalition' means an entity that is a nonprofit organization operated under the direction of a board of directors that is primarily composed of beneficiaries under this title.

''NO PREMIUM FOR ENROLLMENT

''SEC. 1860E. (a) NO PREMIUM FOR ENROLLMENT.—An eligible beneficiary enrolled under the program under this part shall not be responsible for the payment of a premium for such enrollment.

''(b) ANNUAL ENROLLMENT FEE.—

''(1) IN GENERAL.—Subject to paragraph (2), enrollment under the program under this part is conditioned upon payment of an annual enrollment fee of $25.

''(2) INFLATION ADJUSTMENT.—

''(A) IN GENERAL.—For any year after 2005, the annual enrollment fee specified in paragraph (1) is equal to the annual enrollment fee determined under such paragraph (or this paragraph) for the previous year increased by the annual percentage increase described in subparagraph (B).

''(B) ANNUAL PERCENTAGE INCREASE SPECIFIED.—The annual percentage increase specified in this subparagraph for a year is equal to the annual percentage increase in average per capita aggregate expenditures for covered outpatient drugs in the United States for medicare beneficiaries, as determined by the Secretary for the 12-month period ending in July of the previous year.

''(C) ROUNDING.—If any amount determined under subparagraph (A) is not a multiple of $1, such amount shall be rounded to the nearest multiple of $1.

''(3) COLLECTION.—

''(A) IN GENERAL.—Unless the eligible beneficiary makes an election under subparagraph (B), the annual enrollment fee described in paragraph (1) shall be collected and credited to the Prescription Drug Account in a similar manner as the monthly premium determined under section 1839 is collected and credited to the Federal Supplementary Medical Insurance Trust Fund under section 1840.

''(B) DIRECT PAYMENT.—An eligible beneficiary may elect to pay the annual enrollment fee directly to the Secretary or in any other manner approved by the Secretary. The Secretary shall establish procedures for making such an election.

''OUTPATIENT PRESCRIPTION DRUG BENEFITS

''SEC. 1860F. (a) REQUIREMENT.—A plan offered by an eligible entity under this part shall provide eligible beneficiaries enrolled in such plan with—

''(1) coverage of covered outpatient drugs—

''(A) without the application of any deductible; and

''(B) with the cost-sharing described in subsection (b); and

''(2) access to negotiated prices for such drugs under subsection (c).

''(b) COST-SHARING.—

''(1) COINSURANCE FOR FORMULARY DRUGS BEFORE CATASTROPHIC LIMIT REACHED.—Subject to paragraphs (2), (3), and (4), in the case of a covered outpatient drug that is included in the formulary established by the eligible entity (pursuant to section 1860H(c)) for the plan and that is dispensed to an eligible beneficiary, the beneficiary shall be responsible for coinsurance for the drug in an amount equal to the negotiated price for the drug (as reported to the Secretary pursuant to section 1860H(a)(6)(A)) minus 5 percent of such negotiated price.

''(2) BENEFICIARY RESPONSIBLE FOR NEGOTIATED PRICE FOR NONFORMULARY DRUGS BEFORE CATASTROPHIC LIMIT REACHED.—

''(A) IN GENERAL.—In the case of a covered outpatient drug that is not included in the formulary for the plan (and not treated as a brand name drug on the formulary under paragraph (B)) and that is dispensed to an eligible beneficiary in a year before the beneficiary has reached the catastrophic limit under paragraph (3) for the year, the beneficiary shall be responsible for the negotiated price for the drug (as reported to the Secretary pursuant to section 1860H(a)(6)(A)).

''(B) TREATMENT OF MEDICALLY NECESSARY NONFORMULARY DRUGS.—The eligible entity shall treat a drug not included in the formulary for the plan as a brand name drug on the formulary if such nonformulary drug is determined (pursuant to subparagraph (D) or (E) of section 1860H(a)(4)) to be medically necessary, and the beneficiary shall be responsible for the coinsurance described in paragraph (1).

''(3) COPAYMENT ONCE EXPENSES EQUAL ANNUAL CATASTROPHIC LIMIT.—

''(A) IN GENERAL.—Subject to paragraphs (4) and (5), in the case of a covered outpatient drug (regardless of whether it is included in the formulary or not so included) that is dispensed in a year to an eligible beneficiary after the beneficiary has incurred costs (as described in subparagraph (C)) for such drugs in a year equal to the annual catastrophic limit specified in subparagraph (B), the beneficiary shall be responsible for a copayment for the drug in an amount equal to $10 for each prescription (as defined in subparagraph (D)) of such drug.

''(B) ANNUAL CATASTROPHIC LIMIT.—Subject to paragraph (5), for purposes of this part, the 'annual catastrophic limit' specified in this subparagraph is equal to $3,300.

''(C) APPLICATION.—In applying subparagraph (A)—

''(i) incurred costs shall only include costs incurred for the cost-sharing described in this subsection (including the cost-sharing described in paragraph (2)(A)); but

''(ii) such costs shall be treated as incurred only if they are paid by the individual (or by another individual, such as a family member, on behalf of the individual), under title XIX, or by a State pharmacy assistance program,

and the individual (or other individual) is not reimbursed through insurance or otherwise, a group health plan, or other third-party payment arrangement for such costs.

''(D) PRESCRIPTION DEFINED.—

''(i) IN GENERAL.—Subject to clause (ii), for purposes of subparagraph (A), the term 'prescription' means—

''(I) a 30-day supply for a maintenance drug; and

''(II) a supply necessary for the length of the course that is typical of current practice for a nonmaintenance drug.

''(ii) SPECIAL RULE FOR MAIL ORDER DRUGS.—In the case of drugs obtained by mail order, the term 'prescription' may be for a supply that is longer than the period specified in subclause (I) or (II) of clause (i) (as the case may be) if the Secretary determines that the longer supply will not result in an increase in the expenditures made from the Prescription Drug Account.

''(E) COPAYMENT MAY NOT EXCEED NEGOTIATED PRICE.—If the amount of the copayment for a covered outpatient drug that would otherwise be required under this paragraph (but for this subparagraph) is greater than the negotiated price for the drug (as reported to the Secretary pursuant to section 1860H(a)(6)(A)), then the amount of such copayment shall be reduced to an amount equal to such negotiated price.

''(4) REDUCTION BY ELIGIBLE ENTITY.—An eligible entity offering a plan under this part may reduce the coinsurance amount that an eligible beneficiary enrolled in the plan is subject to under paragraph (1) or the copayment amount that such a beneficiary is subject to under paragraph (3) if the Secretary determines that such reduction—

''(A) is tied to the performance requirements described in section 1860I(b)(1)(C); and

''(B) will not result in an increase in the expenditures made from the Prescription Drug Account.

''(5) INFLATION ADJUSTMENT FOR COPAYMENT AND ANNUAL CATASTROPHIC LIMIT.—

''(A) IN GENERAL.—For any year after 2005—

''(i) the copayment amount described in paragraph (3)(A) is equal to the copayment amount determined under such paragraph (or this paragraph) for the previous year, increased by the annual percentage increase described in section 1860E(b)(2)(B); and

''(ii) the annual catastrophic limit specified in paragraph (3)(B) is equal to the annual catastrophic limit determined under such paragraph (or this paragraph) for the previous year increased by the annual percentage increase described in section 1860E(b)(2)(B).

''(B) ROUNDING.—If any amount determined under clause (i) or (ii) of subparagraph (A) is not a multiple of $1, such amount shall be rounded to the nearest multiple of $1.

''(c) ACCESS TO NEGOTIATED PRICES.—

''(1) ACCESS.—Under a plan offered by an eligible entity with a contract under this part, the eligible entity offering such plan shall provide eligible beneficiaries enrolled in such plan with access to negotiated prices (including applicable discounts) used for payment for covered outpatient drugs, regardless of the fact that only partial benefits or no benefits (because of the application of subsection (b)(2)(A)) may be payable under the coverage with respect to such drugs because of the application of the cost-sharing under subsection (b).

''(2) MEDICAID RELATED PROVISIONS.—Insofar as a State elects to provide medical assistance under title XIX for a drug based on the prices negotiated under a plan under this part, the requirements of section 1927 shall not apply to such drugs. The prices negotiated under a plan under this part with respect to covered outpatient drugs, under a Medicare+Choice plan with respect to such drugs, or under a qualified retiree prescription drug plan (as defined in section 1860J(e)(3)) with respect to such drugs, on behalf of eligible beneficiaries, shall (notwithstanding any other provision of law) not be taken into account for the purposes of establishing the best price under section 1927(c)(1)(C).

''ENTITIES ELIGIBLE TO PROVIDE OUTPATIENT DRUG BENEFIT

''SEC. 1860G. (a) ESTABLISHMENT OF PANELS OF PLANS AVAILABLE IN AN AREA.—

''(1) IN GENERAL.—The Secretary shall establish procedures under which the Secretary—

''(A) accepts bids submitted by eligible entities for the plans which such entities intend to offer in an area established under subsection (b); and

''(B) awards contracts to such entities to provide such plans to eligible beneficiaries in the area.

''(2) COMPETITIVE PROCEDURES.—Competitive procedures (as defined in section 4(5) of the Office of Federal Procurement Policy Act (41 U.S.C. 403(5))) shall be used to enter into contracts under this part.

''(b) AREA FOR CONTRACTS.—

''(1) REGIONAL BASIS.—

''(A) IN GENERAL.—Except as provided in subparagraph (B) and subject to paragraph (2), the contract entered into between the Secretary and an eligible entity with respect to a plan shall require the eligible entity to provide coverage of covered outpatient drugs under the plan in a region established by the Secretary under paragraph (2).

''(B) PARTIAL REGIONAL BASIS.—

''(i) IN GENERAL.—If determined appropriate by the Secretary, the Secretary may permit the coverage described in subparagraph (A) to be provided in a partial region determined appropriate by the Secretary.

''(ii) REQUIREMENTS.—If the Secretary permits coverage pursuant to clause (i), the Secretary shall ensure that the partial region in which coverage is provided is—

''(I) at least the size of the commercial service area of the eligible entity for that area; and

''(II) not smaller than a State.

''(2) ESTABLISHMENT OF REGIONS.—

''(A) IN GENERAL.—In establishing regions for contracts under this part, the Secretary shall—

''(i) take into account the number of eligible beneficiaries in an area in order to encourage participation by eligible entities;

''(ii) ensure that there are at least 10 different regions in the United States; and

''(iii) ensure that a region (or partial region under paragraph (1)(B)) would not discriminate based on the health or economic status of potential enrollees.

''(B) NO ADMINISTRATIVE OR JUDICIAL REVIEW.—The establishment of regions and partial regions under this section shall not be subject to administrative or judicial review.

''(c) SUBMISSION OF BIDS.—

''(1) SUBMISSION.—

''(A) IN GENERAL.—Subject to subparagraph (B), each eligible entity desiring to offer a plan under this part in an area shall submit a bid with respect to such plan to the Secretary at such time, in such manner, and accompanied by such information as the Secretary may reasonably require.

''(B) BID THAT COVERS MULTIPLE AREAS.—The Secretary shall permit an eligible entity to submit a single bid for multiple areas if the bid is applicable to all such areas.

''(2) REQUIRED INFORMATION.—The bid described in paragraph (1) shall include—

''(A) a proposal for the estimated negotiated prices of covered outpatient drugs and the projected annual increases in such prices, including differentials between formulary and nonformulary prices, if applicable;

''(B) a statement regarding the amount that the entity will charge the Secretary for managing, administering, and delivering the benefits under the contract;

''(C) a statement regarding whether the entity will reduce the applicable coinsurance or copayment amounts pursuant to section 1860F(b)(4)) and if so, the amount of such reduction and how such reduction is tied to the performance requirements described in section 1860I(b)(1)(C);

''(D) a detailed description of the performance requirements for which the payments to the entity will be subject to risk pursuant to section 1860I(b)(1)(C);

''(E) a detailed description of access to pharmacy services provided under the plan;

''(F) with respect to the formulary used by the entity, a detailed description of the procedures and standards the entity will use for—

''(i) adding new drugs to a therapeutic category or class within the formulary; and

''(ii) determining when and how often the formulary should be modified;

''(G) a detailed description of any ownership or shared financial interests with other entities involved in the delivery of the benefit as proposed under the plan;

''(H) a detailed description of the entity's estimated marketing and advertising expenditures related to enrolling eligible beneficiaries under the plan and retaining such enrollment; and

''(I) such other information that the Secretary determines is necessary in order to carry out this part, including information relating to the bidding process under this part.

''(d) ACCESS TO BENEFITS IN CERTAIN AREAS.—

''(1) AREAS NOT COVERED BY CONTRACTS.—The Secretary shall develop procedures for the provision of covered outpatient drugs under this part to each eligible beneficiary enrolled under this part that resides in an area that is not covered by any contract under this part.

''(2) BENEFICIARIES RESIDING IN DIFFERENT LOCATIONS.—The Secretary shall develop procedures to ensure that each eligible beneficiary enrolled under this part that resides in different areas in a year is provided the benefits under this part throughout the entire year.

''(e) AWARDING OF CONTRACTS.—

''(1) NUMBER OF CONTRACTS.—The Secretary shall, consistent with the requirements of this part and the goal of containing costs under this title, award in a competitive manner at least 2 contracts to offer a plan in an area, unless only 1 bidding entity (and the plan offered by the entity) meets the minimum standards specified under this part and by the Secretary.

''(2) DETERMINATION.—In determining which of the eligible entities that submitted bids that meet the minimum standards specified under this part and by the Secretary to award a contract, the Secretary shall consider the comparative merits of each bid, as determined on the basis of the past performance of the entity and other relevant factors, with respect to—

''(A) how well the entity (and the plan offered by the entity) meet such minimum standards;

''(B) the amount that the entity will charge the Secretary for managing, administering, and delivering the benefits under the contract;

''(C) the performance requirements for which the payments to the entity will be subject to risk pursuant to section 1860I(b)(1)(C);

''(D) the proposed negotiated prices of covered outpatient drugs and annual increases in such prices;

''(E) the factors described in section 1860D(b)(2);

''(F) prior experience of the entity in managing, administering, and delivering a prescription drug benefit program;

''(G) effectiveness of the entity and plan in containing costs through pricing incentives and utilization management; and

''(H) such other factors as the Secretary deems necessary to evaluate the merits of each bid.

''(3) EXCEPTION TO CONFLICT OF INTEREST RULES.—In awarding contracts under this part, the Secretary may waive conflict of interest laws generally applicable to Federal acquisitions (subject to such safeguards as the Secretary may find necessary to impose) in circumstances where the Secretary finds that such waiver—

''(A) is not inconsistent with the—

''(i) purposes of the programs under this title; or

''(ii) best interests of beneficiaries enrolled under this part; and

''(B) permits a sufficient level of competition for such contracts, promotes efficiency of benefits administration, or otherwise serves the objectives of the program under this part.

''(4) NO ADMINISTRATIVE OR JUDICIAL REVIEW.—The determination of the Secretary to award or not award a contract to an eligible entity with respect to a plan under this part shall not be subject to administrative or judicial review.

''(f) APPROVAL OF MARKETING MATERIAL AND APPLICATION FORMS.—The provisions of section 1851(h) shall apply to marketing material and application forms under this part in the same manner as such provisions apply to marketing material and application forms under part C.

''(g) DURATION OF CONTRACTS.—Each contract awarded under this part shall be for a term of at least 2 years but not more than 5 years, as determined by the Secretary.

''(h) FINANCIAL INCENTIVES FOR PHARMACIES TO PARTICIPATE IN CERTAIN PROGRAMS AND SYSTEMS.—The Secretary may establish and provide for incentives for pharmacies to participate in the following:

''(1) COST AND DRUG UTILIZATION MANAGEMENT PROGRAMS.—Effective cost and drug utilization management programs, including such programs that promote appropriate use of generic drugs in order to maximize savings to the program under this part.

''(2) QUALITY ASSURANCE MEASURES AND SYSTEMS.—Quality assurance measures and systems to reduce medical errors.

''(3) PROGRAMS TO CONTROL FRAUD, ABUSE, AND WASTE.—Programs to control fraud, abuse, and waste.

''MINIMUM STANDARDS FOR ELIGIBLE ENTITIES

''SEC. 1860H. (a) IN GENERAL.—The Secretary shall not award a contract to an eligible entity under this part unless the Secretary finds that the eligible entity agrees to comply with such terms and conditions as the Secretary shall specify, including the following:

''(1) QUALITY AND FINANCIAL STANDARDS.—The eligible entity meets the quality and financial standards specified by the Secretary.

''(2) PROCEDURES TO ENSURE PROPER UTILIZATION, COMPLIANCE, AND AVOIDANCE OF ADVERSE DRUG REACTIONS.—

''(A) IN GENERAL.—The eligible entity has in place drug utilization review procedures to ensure—

''(i) the appropriate utilization by eligible beneficiaries enrolled in the plan covered by the contract of the benefits to be provided under the plan;

''(ii) the avoidance of adverse drug reactions among such beneficiaries, including problems due to therapeutic duplication, drug-disease contraindications, drug-drug interactions (including serious interactions with nonprescription or over-the-counter drugs), incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse and misuse; and

''(iii) the reasonable application of peer-reviewed medical literature pertaining to improvements in pharmaceutical safety and appropriate use of drugs.

''(B) AUTHORITY TO USE CERTAIN COMPENDIA AND LITERATURE.—The eligible entity may use the compendia and literature referred to in clauses (i) and (ii), respectively, of section 1927(g)(1)(B) as a source for the utilization review under subparagraph (A).

''(3) ELECTRONIC PRESCRIPTION PROGRAM.—

''(A) IN GENERAL.—The eligible entity has in place, for years beginning with 2006, an electronic prescription drug program that includes at least the following components, consistent with national standards established under subparagraph (B):

''(i) ELECTRONIC TRANSMITTAL OF PRESCRIPTIONS.—Prescriptions are only received electronically, except in emergency cases and other exceptional circumstances recognized by the Secretary.

''(ii) PROVISION OF INFORMATION TO PRESCRIBING HEALTH CARE PROFESSIONAL.—The program provides, upon transmittal of a prescription by a prescribing health care professional, for transmittal by the pharmacist to the professional of information that includes—

''(I) information (to the extent available and feasible) on the drugs being prescribed for that patient and other information relating to the medical history or condition of the patient that may be relevant to the appropriate prescription for that patient;

''(II) cost-effective alternatives (if any) for the use of the drug prescribed; and

''(III) information on the drugs included in the applicable formulary.

To the extent feasible, such program shall permit the prescribing health care professional to provide (and be provided) related information on an interactive, real-time basis.

''(B) STANDARDS.—

''(i) DEVELOPMENT.—The Secretary shall provide for the development of national standards relating to the electronic prescription drug program described in subparagraph (A). Such standards shall be compatible with standards established under part C of title XI.

''(ii) ADVISORY TASK FORCE.—In developing such standards, the Secretary shall establish a task force that includes representatives of physicians, hospitals, pharmacists, and technology experts and representatives of the Departments of Veterans Affairs and Defense and other appropriate Federal agencies to provide recommendations to the Secretary on such standards, including recommendations relating to the following:

''(I) The range of available computerized prescribing software and hardware and their costs to develop and implement.

''(II) The extent to which such systems reduce medication errors and can be readily implemented by physicians and hospitals.

''(III) Efforts to develop a common software platform for computerized prescribing.

''(IV) The cost of implementing such systems in the range of hospital and physician office settings, including hardware, software, and training costs.

''(V) Implementation issues as they relate to part C of title XI, and current Federal and State prescribing laws and regulations and their impact on implementation of computerized prescribing.

''(iii) DEADLINES.—

''(I) The Secretary shall constitute the task force under clause (ii) by not later than April 1, 2003.

''(II) The task force shall submit recommendations to the Secretary by not later than January 1, 2004.

''(III) The Secretary shall develop and promulgate the national standards referred to in clause (ii) by not later than January 1, 2005.

''(C) WAIVER OF APPLICATION FOR CERTAIN RURAL PROVIDERS.—If the Secretary determines that it is unduly burdensome on providers in rural areas to comply with the requirements under this paragraph, the Secretary may waive such requirements for such providers.

''(4) PATIENT PROTECTIONS.—

''(A) ACCESS.—

''(i) IN GENERAL.—The eligible entity ensures that the covered outpatient drugs are accessible and convenient to eligible beneficiaries enrolled in the plan covered by the contract, including by offering the services 24 hours a day and 7 days a week for emergencies.

''(ii) NEGOTIATED PARTICIPATION AGREEMENTS WITH PHARMACIES.—The eligible entity shall negotiate and enter into a participation agreement with any pharmacy that meets the requirements of subsection (d) to dispense covered prescription drugs to eligible beneficiaries under this part. Such agreements shall include the payment of a reasonable dispensing fee for covered outpatient drugs dispensed to a beneficiary under the agreement.

''(iii) PREFERRED PHARMACY NETWORKS.—If the eligible entity utilizes a preferred pharmacy network, the network complies with the standards under subsection (e).

''(B) ENSURING THAT BENEFICIARIES ARE NOT OVERCHARGED.—The eligible entity has procedures in place to ensure that each pharmacy with a negotiated participation agreement under this part with the entity complies with the requirements under subsection (d)(1)(C) (relating to adherence to negotiated prices).

''(C) CONTINUITY OF CARE.—

''(i) IN GENERAL.—The eligible entity ensures that, in the case of an eligible beneficiary who loses coverage under this part with such entity under circumstances that would permit a special election period (as established by the Secretary under section 1860C(a)(1)), the entity will continue to provide coverage under this part to such beneficiary until the beneficiary enrolls and receives such coverage with another eligible entity under this part or, if eligible, with a Medicare+Choice organization.

''(ii) LIMITED PERIOD.—In no event shall an eligible entity be required to provide the extended coverage required under clause (i) beyond the date which is 30 days after the coverage with such entity would have terminated but for this subparagraph.

''(D) PROCEDURES REGARDING THE DETERMINATION OF DRUGS THAT ARE MEDICALLY NECESSARY.—

''(i) IN GENERAL.—The eligible entity has in place procedures on a case-by-case basis to treat a drug not included in the formulary for the plan as a brand name drug on the formulary under this part if the formulary drug for treatment of the same condition is determined—

''(I) to be not as effective for the enrollee as the nonformulary drug in preventing or slowing the deterioration of, or improving or maintaining, the health of the enrollee; or

''(II) to have a significant adverse effect on the enrollee.

''(ii) REQUIREMENT.—The procedures under clause (i) shall require that determinations under such clause are based on professional

medical judgment, the medical condition of the enrollee, and other medical evidence.

''(E) PROCEDURES REGARDING APPEAL RIGHTS WITH RESPECT TO DENIALS OF CARE.—The eligible entity has in place procedures to ensure—

''(i) a timely internal review for resolution of denials of coverage (in whole or in part and including those regarding the coverage of drugs not included on the formulary of the plan as brand name drugs on the formulary) in accordance with the medical exigencies of the case and a timely resolution of complaints, by enrollees in the plan, or by providers, pharmacists, and other individuals acting on behalf of each such enrollee (with the enrollee's consent) in accordance with requirements (as established by the Secretary) that are comparable to such requirements for Medicare+Choice organizations under part C (and are not less favorable to the enrollee than such requirements under such part as in effect on the date of enactment of the Medicare Prescription Drug Cost Protection Act of 2002);

''(ii) that the entity complies in a timely manner with requirements established by the Secretary that (I) provide for an external review by an independent entity selected by the Secretary of denials of coverage described in clause (i) not resolved in the favor of the beneficiary (or other complainant) under the process described in such clause, and (II) are comparable to the external review requirements established for Medicare+Choice organizations under part C (and are not less favorable to the enrollee than such requirements under such part as in effect on the date of enactment of the Medicare Prescription Drug Cost Protection Act of 2002); and

''(iii) that enrollees are provided with information regarding the appeals procedures under this part at the time of enrollment with the entity and upon request thereafter.

''(F) PROCEDURES REGARDING PATIENT CONFIDENTIALITY.—Insofar as an eligible entity maintains individually identifiable medical records or other health information regarding eligible beneficiaries enrolled in the plan that is covered by the contract, the entity has in place procedures to—

''(i) safeguard the privacy of any individually identifiable beneficiary information in a manner consistent with the Federal regulations (concerning the privacy of individually identifiable health information) promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (Public Law 104–191; 110 Stat. 2033);

''(ii) maintain such records and information in a manner that is accurate and timely;

''(iii) ensure timely access by such beneficiaries to such records and information; and

''(iv) otherwise comply with applicable laws relating to patient confidentiality.

''(G) PROCEDURES REGARDING TRANSFER OF MEDICAL RECORDS.—

''(i) IN GENERAL.—The eligible entity has in place procedures for the timely transfer of records and information described in subparagraph (F) (with respect to a beneficiary who loses coverage under this part with the entity and enrolls with another entity (including a Medicare+Choice organization) under this part) to such other entity.

''(ii) PATIENT CONFIDENTIALITY.—The procedures described in clause (i) shall comply with the patient confidentiality procedures described in subparagraph (F).

''(H) PROCEDURES REGARDING MEDICAL ERRORS.—The eligible entity has in place procedures for—

''(i) working with the Secretary to deter medical errors related to the provision of covered outpatient drugs; and

''(ii) ensuring that pharmacies with a contract with the entity have in place procedures to deter medical errors related to the provision of covered outpatient drugs.

''(5) PROCEDURES TO CONTROL FRAUD, ABUSE, AND WASTE.—

''(A) IN GENERAL.—The eligible entity has in place procedures to control fraud, abuse, and waste.

''(B) APPLICABILITY OF FRAUD AND ABUSE PROVISIONS.—The provisions of section 1128 through 1128C (relating to fraud and abuse) apply to eligible entities with contracts under this part.

''(6) REPORTING REQUIREMENTS.—

''(A) IN GENERAL.—The eligible entity provides the Secretary with reports containing information regarding the following:

''(i) The negotiated prices that the eligible entity is paying for covered outpatient drugs.

''(ii) The negotiated prices that eligible beneficiaries enrolled in the plan that is covered by the contract will be charged for covered outpatient drugs.

''(iii) The management costs of providing such benefits.

''(iv) Utilization of such benefits.

''(v) Marketing and advertising expenditures related to enrolling and retaining eligible beneficiaries.

''(B) TIMEFRAME FOR SUBMITTING REPORTS.—

''(i) IN GENERAL.—The eligible entity shall submit a report described in subparagraph (A) to the Secretary within 3 months after the end of each 12-month period in which the eligible entity has a contract under this part. Such report shall contain information concerning the benefits provided during such 12-month period.

''(ii) LAST YEAR OF CONTRACT.—In the case of the last year of a contract under this part, the Secretary may require that a report described in subparagraph (A) be submitted 3 months prior to the end of the contract. Such report shall contain information concerning the benefits provided between the period covered by the most recent report under this subparagraph and the date that a report is submitted under this clause.

''(C) CONFIDENTIALITY OF INFORMATION.—

''(i) IN GENERAL.—Notwithstanding any other provision of law and subject to clause (ii), information disclosed by an eligible entity pursuant to subparagraph (A) (except for information described in clause (ii) of such subparagraph) is confidential and shall only be used by the Secretary for the purposes of, and to the extent necessary, to carry out this part.

''(ii) UTILIZATION DATA.—Subject to patient confidentiality laws, the Secretary shall make information disclosed by an eligible entity pursuant to subparagraph (A)(iv) (regarding utilization data) available for research purposes. The Secretary may charge a reasonable fee for making such information available.

''(7) APPROVAL OF MARKETING MATERIAL AND APPLICATION FORMS.—The eligible entity complies with the requirements described in section 1860G(f).

''(8) RECORDS AND AUDITS.—The eligible entity maintains adequate records related to the management, administration, and delivery of the benefits under this part and affords the Secretary access to such records for auditing purposes.

''(b) SPECIAL RULES REGARDING COST-EFFECTIVE PROVISION OF BENEFITS.—

''(1) IN GENERAL.—In providing the benefits under a contract under this part, an eligible entity shall—

''(A) employ mechanisms to provide the benefits economically, such as through the use of—

''(i) alternative methods of distribution;

''(ii) preferred pharmacy networks (pursuant to subsection (e)); and

''(iii) generic drug substitution;

''(B) use mechanisms to encourage eligible beneficiaries to select cost-effective drugs or less costly means of receiving drugs, such as through the use of—

''(i) pharmacy incentive programs;

''(ii) therapeutic interchange programs; and

''(iii) disease management programs;

''(C) encourage pharmacists to—

''(i) inform beneficiaries of the differentials in price between generic and brand name drug equivalents; and

''(ii) provide medication therapy management programs in order to enhance beneficiaries' understanding of the appropriate use of medications and to reduce the risk of potential adverse events associated with medications; and

''(D) develop and implement a formulary in accordance with subsection (c).

''(2) RESTRICTION.—If an eligible entity uses alternative methods of distribution pursuant to paragraph (1)(A)(i), the entity may not require that a beneficiary use such methods in order to obtain covered outpatient drugs.

''(c) REQUIREMENTS FOR FORMULARIES.—

''(1) STANDARDS.—

''(A) IN GENERAL.—The formulary developed and implemented by the eligible entity shall comply with standards established by the Secretary in consultation with the Medicare Prescription Drug Advisory Committee established under section 1860L.

''(B) NO NATIONAL FORMULARY OR REQUIREMENT TO EXCLUDE SPECIFIC DRUGS.—

''(i) SECRETARY MAY NOT ESTABLISH A NATIONAL FORMULARY.—The Secretary may not establish a national formulary.

''(ii) NO REQUIREMENT TO EXCLUDE SPECIFIC DRUGS.—The standards established by the Secretary pursuant to subparagraph (A) may not require that an eligible entity exclude a specific covered outpatient drug from the formulary developed and implemented by the entity.

''(2) REQUIREMENTS FOR STANDARDS.—The standards established under paragraph (1)(A) shall require that the eligible entity—

''(A) use a pharmacy and therapeutic committee (that meets the standards for a pharmacy and therapeutic committee established by the Secretary in consultation with such Medicare Prescription Drug Advisory Committee) to develop and implement the formulary;

''(B) include in the formulary—

''(i) all generic covered outpatient drugs; and

''(ii) covered outpatient drugs within each therapeutic category and class (as defined by the Secretary in consultation with such Medicare Prescription Drug Advisory Committee) of such drugs, although not necessarily for all drugs within such categories and classes;

''(C) develop procedures for the modification of the formulary, including for the addition of new drugs to an existing therapeutic category or class;

''(D) pursuant to section 1860F(b)(2)(B), provide for the treatment of drugs not included in the formulary for the plan as brand name drugs on the formulary when determined under subparagraph (D) or (E) of subsection (a)(4) to be medically necessary;

''(E) disclose to current and prospective beneficiaries and to providers in the service area the nature of the formulary restrictions, including information regarding the drugs included in the formulary and any difference in the cost-sharing for drugs—

''(i) included in the formulary; and

''(ii) not included in the formulary; and

''(F) provide a reasonable amount of notice to beneficiaries enrolled in the plan that is covered by the contract under this part of any change in the formulary.

''(3) CONSTRUCTION.—Nothing in this part shall be construed as precluding an eligible entity from—

''(A) educating prescribing providers, pharmacists, and beneficiaries about the medical and cost benefits of drugs included in the formulary for the plan (including generic drugs); or

''(B) requesting prescribing providers to consider a drug included in the formulary for the plan prior to dispensing of a drug not so included, as long as such a request does not unduly delay the provision of the drug.

''(d) TERMS OF NEGOTIATED PARTICIPATION AGREEMENT WITH PHARMACIES.—

''(1) IN GENERAL.—A negotiated participation agreement between an eligible entity and a pharmacy under this part (pursuant to subsection (a)(4)(A)(ii)) shall include the following terms and conditions:

''(A) APPLICABLE REQUIREMENTS.—The pharmacy shall meet (and throughout the contract period continue to meet) all applicable Federal requirements and State and local licensing requirements.

''(B) ACCESS AND QUALITY STANDARDS.—The pharmacy shall comply with such standards as the Secretary (and the eligible entity) shall establish concerning the quality of, and enrolled beneficiaries' access to, pharmacy services under this part. Such standards shall require the pharmacy—

''(i) not to refuse to dispense covered outpatient drugs to any eligible beneficiary enrolled under this part;

''(ii) to keep patient records (including records on expenses) for all covered outpatient drugs dispensed to such enrolled beneficiaries;

''(iii) to submit information (in a manner specified by the Secretary to be necessary to administer this part) on all purchases of such drugs dispensed to such enrolled beneficiaries; and

''(iv) to comply with periodic audits to assure compliance with the requirements of this part and the accuracy of information submitted.

''(C) ENSURING THAT BENEFICIARIES ARE NOT OVERCHARGED.—

''(i) ADHERENCE TO NEGOTIATED PRICES.—The total charge for each covered outpatient drug dispensed by the pharmacy to a beneficiary enrolled in the plan, without regard to whether the individual is financially responsible for any or all of such charge, shall not exceed the negotiated price for the drug (as reported to the Secretary pursuant to subsection (a)(6)(A)).

''(ii) ADHERENCE TO BENEFICIARY OBLIGATION.—The pharmacy may not charge (or collect from) such beneficiary an amount that exceeds the cost-sharing that the beneficiary is responsible for under this part (as determined under section 1860F(b) using the negotiated price of the drug).

''(D) ADDITIONAL REQUIREMENTS.—The pharmacy shall meet such additional contract requirements as the eligible entity specifies under this section.

''(2) APPLICABILITY OF FRAUD AND ABUSE PROVISIONS.—The provisions of section 1128 through 1128C (relating to fraud and abuse) apply to pharmacies participating in the program under this part.

''(e) PREFERRED PHARMACY NETWORKS.—

''(1) IN GENERAL.—If an eligible entity uses a preferred pharmacy network to deliver benefits under this part, such network shall meet minimum access standards established by the Secretary.

''(2) STANDARDS.—In establishing standards under paragraph (1), the Secretary shall take into account reasonable distances to pharmacy services in both urban and rural areas.

''PAYMENTS

''SEC. 1860I. (a) PROCEDURES FOR PAYMENTS TO ELIGIBLE ENTITIES.—The Secretary shall establish procedures for making payments to each eligible entity with a contract to offer a plan under this part for the management, administration, and delivery of the benefits under the plan.

''(b) REQUIREMENTS FOR PROCEDURES.—

''(1) IN GENERAL.—The procedures established under subsection (a) shall provide for the following:

''(A) MANAGEMENT PAYMENT.—Payment for the management, administration, and delivery of the benefits under the plan.

''(B) REIMBURSEMENT FOR NEGOTIATED COSTS OF DRUGS PROVIDED.—Payments for the negotiated costs of covered outpatient drugs provided to eligible beneficiaries enrolled under this part and in the plan, reduced by any applicable cost-sharing under section 1860F(b).

''(C) RISK REQUIREMENT TO ENSURE PURSUIT OF PERFORMANCE REQUIREMENTS.—An adjustment of a percentage (as determined under paragraph (3)) of the payments made to an entity under subparagraph (A) to ensure that the entity, in managing, administering, and delivering the benefits under the plan, pursues performance requirements established by the Secretary, including the following:

''(i) CONTROL OF MEDICARE AND BENEFICIARY COSTS.—The entity contains costs to the Prescription Drug Account and to eligible beneficiaries enrolled under this part and in the plan, as measured by generic substitution rates, price discounts, and other factors determined appropriate by the Secretary that do not reduce the access of such beneficiaries to medically necessary covered outpatient drugs.

''(ii) QUALITY CLINICAL CARE.—The entity provides such beneficiaries with quality clinical care, as measured by such factors as—

''(I) the level of adverse drug reactions and medical errors among such beneficiaries; and

''(II) providing specific clinical suggestions to improve health and patient and prescriber education as appropriate.

''(iii) QUALITY SERVICE.—The entity provides such beneficiaries with quality services, as measured by such factors as sustained pharmacy network access, timeliness and accuracy of service delivery in claims processing and card production, pharmacy and member service support access, response time in mail delivery service, and timely action with regard to appeals and current beneficiary service surveys.

''(2) SECRETARY TO CONSIDER RISK PROFILE OF ENROLLEES.—The Secretary shall take into account the risk profile of beneficiaries enrolled under this part and in the plan in assessing the degree to which the entity is meeting the performance requirements under paragraph (1)(C).

''(3) PERCENTAGE OF PAYMENT TIED TO RISK.—

''(A) IN GENERAL.—Subject to subparagraph (B), the Secretary shall determine the percentage (which may be up to 100 percent) of the payments made to an entity under paragraph (1)(A) that will be tied to the performance requirements described in paragraph (1)(C).

''(B) LIMITATION ON RISK TO ENSURE PROGRAM STABILITY.—In order to provide for program stability, the Secretary may not establish a percentage to be adjusted under this subsection at a level that jeopardizes the ability of an eligible entity to administer and deliver the benefits under this part or administer and deliver such benefits in a quality manner.

''(4) PASS-THROUGH OF REBATES, DISCOUNTS, AND PRICE CONCESSIONS OBTAINED BY THE ELIGIBLE ENTITY.—The Secretary shall establish procedures for reducing the amount of payments to an eligible entity under paragraph (1) to take into account any rebates, discounts, or price concessions obtained by the entity from manufacturers of covered outpatient drugs, unless the Secretary determines that such procedures are not in the best interests of the medicare program or eligible beneficiaries.

''(c) PAYMENTS TO MEDICARE+CHOICE ORGANIZATIONS.—For provisions related to payments to Medicare+Choice organizations for the management, administration, and delivery of benefits under this part to eligible beneficiaries enrolled in a Medicare+Choice plan offered by the organization, see section 1853(c)(8).

''(d) SECONDARY PAYER PROVISIONS.—The provisions of section 1862(b) shall apply to the benefits provided under this part.

''EMPLOYER INCENTIVE PROGRAM FOR EMPLOYMENT-BASED RETIREE DRUG COVERAGE

''SEC. 1860J. (a) PROGRAM AUTHORITY.—The Secretary is authorized to develop and implement a program under this section to be known as the 'Employer Incentive Program' that encourages employers and other sponsors of employment-based health care coverage to provide adequate prescription drug benefits to retired individuals by subsidizing, in part, the sponsor's cost of providing coverage under qualifying plans.

''(b) SPONSOR REQUIREMENTS.—In order to be eligible to receive an incentive payment under this section with respect to coverage of an individual under a qualified retiree prescription drug plan (as defined in subsection (e)(3)), a sponsor shall meet the following requirements:

''(1) ASSURANCES.—The sponsor shall—

''(A) annually attest, and provide such assurances as the Secretary may require, that the coverage offered by the sponsor is a qualified retiree prescription drug plan, and will remain such a plan for the duration of the sponsor's participation in the program under this section; and

''(B) guarantee that it will give notice to the Secretary and covered retirees—

''(i) at least 120 days before terminating its plan; and

''(ii) immediately upon determining that the actuarial value of the prescription drug benefit under the plan falls below the actuarial value of the outpatient prescription drug benefit under this part.

''(2) BENEFICIARY INFORMATION.—The sponsor shall report to the Secretary, for each calendar quarter for which it seeks an incentive payment under this section, the names and social security numbers of all retirees (and their spouses and dependents) covered under such plan during such quarter and the dates (if less than the full quarter) during which each such individual was covered.

''(3) AUDITS.—The sponsor and the employment-based retiree health coverage plan seeking incentive payments under this section shall agree to maintain, and to afford the Secretary access to, such records as the Secretary may require for purposes of audits and other oversight activities necessary to ensure the adequacy of prescription drug coverage, the accuracy of incentive payments made, and such other matters as may be appropriate.

''(4) OTHER REQUIREMENTS.—The sponsor shall provide such other information, and comply with such other requirements, as the Secretary may find necessary to administer the program under this section.

''(c) INCENTIVE PAYMENTS.—

''(1) IN GENERAL.—A sponsor that meets the requirements of subsection (b) with respect to a quarter in a calendar year shall be entitled to have payment made by the Secretary

on a quarterly basis (to the sponsor or, at the sponsor's direction, to the appropriate employment-based health plan) of an incentive payment, in the amount determined in paragraph (2), for each retired individual (or spouse or dependent) who—

''(A) was covered under the sponsor's qualified retiree prescription drug plan during such quarter; and

''(B) was eligible for, but was not enrolled in, the outpatient prescription drug benefit program under this part.

''(2) AMOUNT OF PAYMENT.—

''(A) IN GENERAL.—The amount of the payment for a quarter shall be, for each individual described in paragraph (1), ¾ of the sum of the monthly Government contribution amounts (computed under subparagraph (B)) for each of the 3 months in the quarter.

''(B) COMPUTATION OF MONTHLY GOVERNMENT CONTRIBUTION AMOUNT.—For purposes of subparagraph (A), the monthly Government contribution amount for a month in a year is equal to the amount by which—

''(i) 1/12 of the amount estimated under subparagraph (C) for the year involved; exceeds

''(ii) 1/12 of the annual enrollment fee for the year under section 1860E(b).

''(C) ESTIMATE OF AVERAGE ANNUAL PER CAPITA AGGREGATE EXPENDITURES.—

''(i) IN GENERAL.—The Secretary shall for each year after 2004 estimate for that year an amount equal to average annual per capita aggregate expenditures payable from the Prescription Drug Account for that year.

''(ii) TIMEFRAME FOR ESTIMATION.—The Secretary shall make the estimate described in clause (i) for a year before the beginning of that year.

''(3) PAYMENT DATE.—The payment under this section with respect to a calendar quarter shall be payable as of the end of the next succeeding calendar quarter.

''(d) CIVIL MONEY PENALTIES.—A sponsor, health plan, or other entity that the Secretary determines has, directly or through its agent, provided information in connection with a request for an incentive payment under this section that the entity knew or should have known to be false shall be subject to a civil monetary penalty in an amount up to 3 times the total incentive amounts under subsection (c) that were paid (or would have been payable) on the basis of such information.

''(e) DEFINITIONS.—In this section:

''(1) EMPLOYMENT-BASED RETIREE HEALTH COVERAGE.—The term 'employment-based retiree health coverage' means health insurance or other coverage, whether provided by voluntary insurance coverage or pursuant to statutory or contractual obligation, of health care costs for retired individuals (or for such individuals and their spouses and dependents) based on their status as former employees or labor union members.

''(2) EMPLOYER.—The term 'employer' has the meaning given the term in section 3(5) of the Employee Retirement Income Security Act of 1974 (except that such term shall include only employers of 2 or more employees).

''(3) QUALIFIED RETIREE PRESCRIPTION DRUG PLAN.—The term 'qualified retiree prescription drug plan' means health insurance coverage included in employment-based retiree health coverage that—

''(A) provides coverage of the cost of prescription drugs with an actuarial value (as defined by the Secretary) to each retired beneficiary that equals or exceeds the actuarial value of the benefits provided to an individual enrolled in the outpatient prescription drug benefit program under this part; and

''(B) does not deny, limit, or condition the coverage or provision of prescription drug benefits for retired individuals based on age or any health status-related factor described in section 2702(a)(1) of the Public Health Service Act.

''(4) SPONSOR.—The term 'sponsor' has the meaning given the term 'plan sponsor' in section 3(16)(B) of the Employer Retirement Income Security Act of 1974.

''(f) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated from time to time, out of any moneys in the Treasury not otherwise appropriated, such sums as may be necessary to carry out the program under this section.

''PRESCRIPTION DRUG ACCOUNT IN THE FEDERAL SUPPLEMENTARY MEDICAL INSURANCE TRUST FUND

''SEC. 1860K. (a) ESTABLISHMENT.—

''(1) IN GENERAL.—There is created within the Federal Supplementary Medical Insurance Trust Fund established by section 1841 an account to be known as the 'Prescription Drug Account' (in this section referred to as the 'Account').

''(2) FUNDS.—The Account shall consist of such gifts and bequests as may be made as provided in section 201(i)(1), and such amounts as may be deposited in, or appropriated to, the account as provided in this part.

''(3) SEPARATE FROM REST OF TRUST FUND.—Funds provided under this part to the Account shall be kept separate from all other funds within the Federal Supplementary Medical Insurance Trust Fund.

''(b) PAYMENTS FROM ACCOUNT.—

''(1) IN GENERAL.—The Managing Trustee shall pay from time to time from the Account such amounts as the Secretary certifies are necessary to make payments to operate the program under this part, including payments to eligible entities under section 1860I, payments to Medicare+Choice organizations under section 1853(c)(8), and payments with respect to administrative expenses under this part in accordance with section 201(g).

''(2) TREATMENT IN RELATION TO PART B PREMIUM.—Amounts payable from the Account shall not be taken into account in computing actuarial rates or premium amounts under section 1839.

''(c) APPROPRIATIONS TO COVER BENEFITS AND ADMINISTRATIVE COSTS.—There are appropriated to the Account in a fiscal year, out of any moneys in the Treasury not otherwise appropriated, an amount equal to the amount by which the benefits and administrative costs of providing the benefits under this part in the year exceed the annual enrollment fees collected under section 1860E(b) for the year.

''MEDICARE PRESCRIPTION DRUG ADVISORY COMMITTEE

''SEC. 1860L. (a) ESTABLISHMENT OF COMMITTEE.—There is established a Medicare Prescription Drug Advisory Committee (in this section referred to as the 'Committee').

''(b) FUNCTIONS OF COMMITTEE.—On and after January 1, 2004, the Committee shall advise the Secretary on policies related to—

''(1) the development of guidelines for the implementation and administration of the outpatient prescription drug benefit program under this part; and

''(2) the development of—

''(A) standards for a pharmacy and therapeutics committee required of eligible entities under section 1860H(c)(2)(A);

''(B) standards required under subparagraphs (D) and (E) of section 1860H(a)(4) for determining if a drug is medically necessary;

''(C) standards for—

''(i) establishing therapeutic categories and classes of covered outpatient drugs;

''(ii) adding new therapeutic categories and classes of covered outpatient drugs to a formulary; and

''(iii) defining maintenance and nonmaintenance drugs and determining the length of the course that is typical of current practice for nonmaintenance drugs for purposes of applying section 1860F(b)(3);

''(D) procedures to evaluate the bids submitted by eligible entities under this part; and

''(E) procedures to ensure that eligible entities with a contract under this part are in compliance with the requirements under this part.

''(c) STRUCTURE AND MEMBERSHIP OF THE COMMITTEE.—

''(1) STRUCTURE.—The Committee shall be composed of 19 members who shall be appointed by the Secretary.

''(2) MEMBERSHIP.—

''(A) IN GENERAL.—The members of the Committee shall be chosen on the basis of their integrity, impartiality, and good judgment, and shall be individuals who are, by reason of their education, experience, attainments, and understanding of pharmaceutical cost control and quality enhancement, exceptionally qualified to perform the duties of members of the Committee.

''(B) SPECIFIC MEMBERS.—Of the members appointed under paragraph (1)—

''(i) five shall be chosen to represent physicians, 2 of whom shall be geriatricians;

''(ii) two shall be chosen to represent nurse practitioners;

''(iii) four shall be chosen to represent pharmacists;

''(iv) one shall be chosen to represent the Centers for Medicare & Medicaid Services;

''(v) four shall be chosen to represent actuaries, pharmacoeconomists, researchers, and other appropriate experts;

''(vi) one shall be chosen to represent emerging drug technologies;

''(vii) one shall be chosen to represent the Food and Drug Administration; and

''(viii) one shall be chosen to represent individuals enrolled under this part.

''(d) TERMS OF APPOINTMENT.—Each member of the Committee shall serve for a term determined appropriate by the Secretary. The terms of service of the members initially appointed shall begin on March 1, 2003.

''(e) CHAIRPERSON.—The Secretary shall designate a member of the Committee as Chairperson. The term as Chairperson shall be for a 1-year period.

''(f) COMMITTEE PERSONNEL MATTERS.—

''(1) MEMBERS.—

''(A) COMPENSATION.—Each member of the Committee who is not an officer or employee of the Federal Government shall be compensated at a rate equal to the daily equivalent of the annual rate of basic pay prescribed for level IV of the Executive Schedule under section 5315 of title 5, United States Code, for each day (including travel time) during which such member is engaged in the performance of the duties of the Committee. All members of the Committee who are officers or employees of the United States shall serve without compensation in addition to that received for their services as officers or employees of the United States.

''(B) TRAVEL EXPENSES.—The members of the Committee shall be allowed travel expenses, including per diem in lieu of subsistence, at rates authorized for employees of agencies under subchapter I of chapter 57 of title 5, United States Code, while away from their homes or regular places of business in the performance of services for the Committee.

''(2) STAFF.—The Committee may appoint such personnel as the Committee considers appropriate.

''(g) OPERATION OF THE COMMITTEE.—

''(1) MEETINGS.—The Committee shall meet at the call of the Chairperson (after consultation with the other members of the

Committee) not less often than quarterly to consider a specific agenda of issues, as determined by the Chairperson after such consultation.

''(2) QUORUM.—Ten members of the Committee shall constitute a quorum for purposes of conducting business.

''(h) FEDERAL ADVISORY COMMITTEE ACT.—Section 14 of the Federal Advisory Committee Act (5 U.S.C. App.) shall not apply to the Committee.

''(i) TRANSFER OF PERSONNEL, RESOURCES, AND ASSETS.—For purposes of carrying out its duties, the Secretary and the Committee may provide for the transfer to the Committee of such civil service personnel in the employ of the Department of Health and Human Services (including the Centers for Medicare & Medicaid Services), and such resources and assets of the Department used in carrying out this title, as the Committee requires.

''(j) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary to carry out the purposes of this section.''.

(b) EXCLUSIONS FROM COVERAGE.—

(1) APPLICATION TO PART D.—Section 1862(a) of the Social Security Act (42 U.S.C. 1395y(a)) is amended in the matter preceding paragraph (1) by striking ''part A or part B'' and inserting ''part A, B, or D''.

(2) PRESCRIPTION DRUGS NOT EXCLUDED FROM COVERAGE IF REASONABLE AND NECESSARY.—Section 1862(a)(1) of the Social Security Act (42 U.S.C. 1395y(a)(1)) is amended—

(A) in subparagraph (H), by striking ''and'' at the end;

(B) in subparagraph (I), by striking the semicolon at the end and inserting '', and''; and

(C) by adding at the end the following new subparagraph:

''(J) in the case of prescription drugs covered under part D, which are not reasonable and necessary to prevent or slow the deterioration of, or improve or maintain, the health of eligible beneficiaries;''.

(c) CONFORMING AMENDMENTS TO FEDERAL SUPPLEMENTARY MEDICAL INSURANCE TRUST FUND.—Section 1841 of the Social Security Act (42 U.S.C. 1395t) is amended—

(1) in the last sentence of subsection (a)—

(A) by striking ''and'' before ''such amounts''; and

(B) by inserting before the period the following: '', and such amounts as may be deposited in, or appropriated to, the Prescription Drug Account established by section 1860K'';

(2) in subsection (g), by inserting after ''by this part,'' the following: ''the payments provided for under part D (in which case the payments shall be made from the Prescription Drug Account in the Trust Fund),'';

(3) in subsection (h), by inserting after ''1840(d)'' the following: ''and section 1860E(b)(3) (in which case the payments shall be made from the Prescription Drug Account in the Trust Fund)''; and

(4) in subsection (i), by inserting after ''section 1840(b)(1)'' the following: '', section 1860E(b)(3) (in which case the payments shall be made from the Prescription Drug Account in the Trust Fund),''.

(d) CONFORMING REFERENCES TO PREVIOUS PART D.—

(1) IN GENERAL.—Any reference in law (in effect before the date of enactment of this Act) to part D of title XVIII of the Social Security Act is deemed a reference to part E of such title (as in effect after such date).

(2) SECRETARIAL SUBMISSION OF LEGISLATIVE PROPOSAL.—Not later than 6 months after the date of enactment of this Act, the Secretary of Health and Human Services shall submit to Congress a legislative proposal providing for such technical and conforming amendments in the law as are required by the provisions of this title.

SEC. 203. PART D BENEFITS UNDER MEDICARE+CHOICE PLANS.

(a) ELIGIBILITY, ELECTION, AND ENROLLMENT.—Section 1851 of the Social Security Act (42 U.S.C. 1395w–21) is amended—

(1) in subsection (a)(1)(A), by striking ''parts A and B'' and inserting ''parts A, B, and D''; and

(2) in subsection (i)(1), by striking ''parts A and B'' and inserting ''parts A, B, and D''.

(b) VOLUNTARY BENEFICIARY ENROLLMENT FOR DRUG COVERAGE.—Section 1852(a)(1)(A) of the Social Security Act (42 U.S.C. 1395w–22(a)(1)(A)) is amended by inserting ''(and under part D to individuals also enrolled under that part)'' after ''parts A and B''.

(c) ACCESS TO SERVICES.—Section 1852(d)(1) of the Social Security Act (42 U.S.C. 1395w–22(d)(1)) is amended—

(1) in subparagraph (D), by striking ''and'' at the end;

(2) in subparagraph (E), by striking the period at the end and inserting ''; and''; and

(3) by adding at the end the following new subparagraph:

''(F) in the case of covered outpatient drugs (as defined in section 1860(1)) provided to individuals enrolled under part D, the organization complies with the access requirements applicable under part D.''.

(d) PAYMENTS TO ORGANIZATIONS FOR PART D BENEFITS.—

(1) IN GENERAL.—Section 1853(a)(1)(A) of the Social Security Act (42 U.S.C. 1395w–23(a)(1)(A)) is amended—

(A) by inserting ''determined separately for the benefits under parts A and B and under part D (for individuals enrolled under that part)'' after ''as calculated under subsection (c)'';

(B) by striking ''that area, adjusted for such risk factors'' and inserting ''that area. In the case of payment for the benefits under parts A and B, such payment shall be adjusted for such risk factors as''; and

(C) by inserting before the last sentence the following: ''In the case of the payments under subsection (c)(8) for the provision of coverage of covered outpatient drugs to individuals enrolled under part D, such payment shall be adjusted for the risk factors of each enrollee as the Secretary determines to be feasible and appropriate to ensure actuarial equivalence.''.

(2) AMOUNT.—Section 1853(c) of the Social Security Act (42 U.S.C. 1395w–23(c)) is amended—

(A) in paragraph (1), in the matter preceding subparagraph (A), by inserting ''for benefits under parts A and B'' after ''capitation rate''; and

(B) by adding at the end the following new paragraph:

''(8) CAPITATION RATE FOR PART D BENEFITS.—

''(A) IN GENERAL.—In the case of a Medicare+Choice plan that provides coverage of covered outpatient drugs to an individual enrolled under part D, the capitation rate for such coverage shall be the amount described in subparagraph (B). Such payments shall be made in the same manner and at the same time as the payments to the Medicare+Choice organization offering the plan for benefits under parts A and B are otherwise made, but such payments shall be payable from the Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund under section 1841.

''(B) AMOUNT.—The amount described in this paragraph is an amount equal to 1/12 of the average annual per capita aggregate expenditures payable from the Prescription Drug Account for the year (as estimated under section 1860J(c)(2)(C)).''.

(e) LIMITATION ON ENROLLEE LIABILITY.—Section 1854(e) of the Social Security Act (42 U.S.C. 1395w–24(e)) is amended by adding at the end the following new paragraph:

''(5) SPECIAL RULE FOR PART D BENEFITS.—With respect to outpatient prescription drug benefits under part D, a Medicare+Choice organization may not require that an enrollee pay any deductible or pay a cost-sharing amount that exceeds the amount of cost-sharing applicable for such benefits for an eligible beneficiary under part D.''.

(f) REQUIREMENT FOR ADDITIONAL BENEFITS.—Section 1854(f)(1) of the Social Security Act (42 U.S.C. 1395w–24(f)(1)) is amended by adding at the end the following new sentence: ''Such determination shall be made separately for the benefits under parts A and B and for prescription drug benefits under part D.''.

(g) EFFECTIVE DATE.—The amendments made by this section shall apply to items and services provided under a Medicare+Choice plan on or after January 1, 2005.

SEC. 204. ADDITIONAL ASSISTANCE FOR LOW-INCOME BENEFICIARIES.

(a) INCLUSION IN MEDICARE COST-SHARING.—

(1) IN GENERAL.—Section 1905(p)(3) of the Social Security Act (42 U.S.C. 1396d(p)(3)) is amended—

(A) in subparagraph (B), by inserting ''and, subject to paragraph (7), cost-sharing described in section 1860F(b), subject to payment by the individual of a cost-sharing charge for the dispensing of a covered outpatient drug (as defined in section 1860(1)) that is equal to $2 for a prescription (as defined in section 1860F(b)(3)(D)) of a generic drug and $5 for a prescription (as so defined) of a brand name drug'' after ''section 1813''; and

(B) by inserting after subparagraph (D) the following new subparagraph:

''(E) The annual enrollment fee under section 1860E(b).''.

(2) INDEXING.—Section 1905(p) of the Social Security Act (42 U.S.C. 1396d(p)) is amended—

(A) by redesignating paragraph (6) as paragraph (8); and

(B) by inserting after paragraph (5) the following new paragraph:

''(6)(A) For any year after 2005, the cost-sharing amounts specified in paragraph (3)(B) for covered outpatient drugs (as defined in section 1860(1)) are equal to the cost-sharing amounts for such drugs determined under such paragraph (or this paragraph) for the previous year increased by the annual percentage increase described in section 1860E(b)(2)(B).

''(B) If any amount determined under subparagraph (A) is not a multiple of $1, such amount shall be rounded to the nearest multiple of $1.''.

(b) EXPANSION OF MEDICAL ASSISTANCE.—Section 1902(a)(10)(E) of the Social Security Act (42 U.S.C. 1396a(a)(10)(E)) is amended—

(1) in clause (iii)—

(A) by inserting after ''section 1905(p)(3)(A)(ii)'' the following: '', for medicare cost-sharing described in section 1905(p)(3)(B) (but only insofar as it relates to benefits provided under part D of title XVIII), and for medicare cost-sharing described in section 1905(p)(3)(E),''; and

(B) by striking ''and'' at the end;

(2) by redesignating clause (iv) as clause (v); and

(3) by inserting after clause (iii) the following new clause:

''(iv) for making medical assistance available for medicare cost-sharing described in section 1905(p)(3)(B) (but only insofar as it relates to benefits provided under part D of title XVIII) and for medicare cost-sharing described in section 1905(p)(3)(E) for—

''(I) individuals who would be qualified medicare beneficiaries described in section 1905(p)(1) but for the fact that their income exceeds 120 percent but does not exceed 150 percent of the official poverty line (referred to in section 1905(p)(2)) for a family of the size involved; and

''(II) individuals who would be qualified medicare beneficiaries described in section 1905(p)(1) but for the fact that their income exceeds 150 percent but does not exceed 200 percent of the official poverty line (referred to in section 1905(p)(2)) for a family of the size involved; and''.

(c) NONDISCRIMINATION.—Section 1905(p) of the Social Security Act (42 U.S.C. 1396d(p)), as amended by subsection (a)(2), is amended by inserting after paragraph (6) the following new paragraph:

''(7) With respect to determining the eligibility of individuals described in clause (i), (iii), or (iv) of section 1902(a)(10)(E) for medicare cost-sharing described in paragraph (3)(B) (but only insofar as it relates to benefits provided under part D of title XVIII) and for medicare cost-sharing described in paragraph (3)(E), the State shall—

''(A) use the same methodology in determining income eligibility for all such individuals;

''(B) use the same simplified eligibility form (including, if applicable, permitting application other than in person) for all such individuals;

''(C) provide for initial eligibility determinations and redeterminations and renewals of eligibility using the same verification policies, forms, and frequency for all such individuals; and

''(D) use the same face-to-face interview policy (including, if applicable, not requiring such an interview) for purposes of initial eligibility determinations and redeterminations, and renewals for all such individuals.''.

(d) NONAPPLICABILITY OF RESOURCE REQUIREMENTS TO MEDICARE PART D COST-SHARING.—Section 1905(p)(1) of the Social Security Act (42 U.S.C. 1396d(p)(1)) is amended by adding at the end the following flush sentence:

''In determining if an individual is a qualified medicare beneficiary under this paragraph, subparagraph (C) shall not be applied for purposes of providing the individual with medicare cost-sharing described in section 1905(p)(3)(B) (but only insofar as it relates to benefits provided under part D of title XVIII) or with medicare cost-sharing described in section 1905(p)(3)(E).''.

(e) NONAPPLICABILITY OF PAYMENT DIFFERENTIAL REQUIREMENTS TO MEDICARE PART D COST-SHARING.—Section 1902(n)(2) of the Social Security Act (42 U.S.C. 1396a(n)(2)) is amended by adding at the end the following new sentence: ''The preceding sentence shall not apply to the cost-sharing described in section 1860F(b).''.

(f) INCREASED FEDERAL MATCHING ASSISTANCE PERCENTAGE FOR CERTAIN INDIVIDUALS.—

(1) USE OF ENHANCED FMAP FOR INDIVIDUALS WITH INCOMES THAT EXCEED 120 PERCENT, BUT DO NOT EXCEED 150 PERCENT, OF THE POVERTY LINE.—The first sentence of section 1905(b) of the Social Security Act (42 U.S.C. 1396d(b)(4)) is amended—

(A) in paragraph (4), by inserting ''(A)'' after ''2105(b)''; and

(B) by inserting before the period at the end the following: '', and (B) with respect to medicare cost-sharing described in subparagraph (B) of section 1905(p)(3) (but only insofar as it relates to benefits provided under part D of title XVIII) and medicare cost-sharing described in subparagraph (E) of that section, but only in the case of individuals who are eligible for such assistance on the basis of clause (iv)(I) of section 1902(a)(10)(E)''.

(2) 100 PERCENT FEDERAL MATCHING ASSISTANCE PERCENTAGE FOR INDIVIDUALS WITH INCOMES THAT EXCEED 150 PERCENT, BUT DO NOT EXCEED 200 PERCENT, OF THE POVERTY LINE.—The first sentence of section 1905(b) of the Social Security Act (42 U.S.C. 1396d(b)(4)), as amended by paragraph (1), is amended—

(A) by striking ''and'' before ''(4)''; and

(B) by inserting before the period at the end the following: '', and (5) the Federal medical assistance percentage shall be 100 percent with respect to medicare cost-sharing described in subparagraph (B) of section 1905(p)(3) (but only insofar as it relates to benefits provided under part D of title XVIII) and medicare cost-sharing described in subparagraph (E) of that section, but only in the case of individuals who are eligible for such assistance on the basis of clause (iv)(II) of section 1902(a)(10)(E)''.

(g) TREATMENT OF TERRITORIES.—Section 1108(g) of the Social Security Act (42 U.S.C. 1308(g)) is amended by adding at the end the following new paragraph:

''(3) Notwithstanding the preceding provisions of this subsection, with respect to fiscal year 2005 and any fiscal year thereafter, the amount otherwise determined under this subsection (and subsection (f)) for the fiscal year for a Commonwealth or territory shall be increased by the ratio (as estimated by the Secretary) of—

''(A) the aggregate amount of payments made to the 50 States and the District of Columbia for the fiscal year under title XIX that are attributable to making medical assistance available for individuals described in clauses (i), (iii), and (iv) of section 1902(a)(10)(E) for payment of medicare cost-sharing described in section 1905(p)(3)(B) (but only insofar as it relates to benefits provided under part D of title XVIII) and medicare cost-sharing described in section 1905(p)(3)(E); to

''(B) the aggregate amount of total payments made to such States and District for the fiscal year under such title XIX.''.

(h) AMENDMENT TO BEST PRICE.—Section 1927(c)(1)(C)(i) of the Social Security Act (42 U.S.C. 1396r–8(c)(1)(C)(i)) is amended—

(1) by striking ''and'' at the end of subclause (III);

(2) by striking the period at the end of subclause (IV) and inserting ''; and''; and

(3) by adding at the end the following new subclause:

''(V) any prices charged which are negotiated under a plan under part D of title XVIII with respect to covered outpatient drugs, under a Medicare+Choice plan under part C of such title with respect to such drugs, or by a qualified retiree prescription drug plan (as defined in section 1860J(e)(3)) with respect to such drugs, on behalf of eligible beneficiaries (as defined in section 1860(2)).''.

(i) CONFORMING AMENDMENTS.—Section 1933 of the Social Security Act (42 U.S.C. 1396u–3) is amended—

(1) in subsection (a), by striking ''section 1902(a)(10)(E)(iv)'' and inserting ''section 1902(a)(10)(E)(v)'';

(2) in subsection (c)(2)(A)—

(A) in clause (i), by striking ''section 1902(a)(10)(E)(iv)(I)'' and inserting ''section 1902(a)(10)(E)(v)(I)''; and

(B) in clause (ii), by striking ''section 1902(a)(10)(E)(iv)(II)'' and inserting ''section 1902(a)(10)(E)(v)(II)'';

(3) in subsection (d), by striking ''section 1902(a)(10)(E)(iv)'' and inserting ''section 1902(a)(10)(E)(v)''; and

(4) in subsection (e), by striking ''section 1902(a)(10)(E)(iv)'' and inserting ''section 1902(a)(10)(E)(v)''.

(j) EFFECTIVE DATE.—The amendments made by this section shall apply to medical assistance provided under section 1902(a)(10)(E) of the Social Security Act (42 U.S.C. 1396a(a)(10)(E)) on and after January 1, 2005.

(k) RULE OF CONSTRUCTION.—Nothing in the amendments made by this section shall be construed as precluding a State from using State funds to provide coverage of outpatient prescription drugs that is in addition to the coverage of such drugs required under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.), as amended by this section.

(l) SENSE OF THE SENATE.—It is the sense of the Senate that during consideration of any conference report for this legislation, conferees should explore ways to provide incentives to States (and in particular to those States that, as of the date of enactment of this Act, offer some form of prescription drug assistance to the elderly and the disabled) to maintain existing State commitments to provide prescription drug assistance to the elderly and disabled or to supplement the drug benefit established by the conference report.

SEC. 205. MEDIGAP REVISIONS.

Section 1882 of the Social Security Act (42 U.S.C. 1395ss) is amended by adding at the end the following new subsection:

''(v) MODERNIZED BENEFIT PACKAGES FOR MEDICARE SUPPLEMENTAL POLICIES.—

''(1) REVISION OF BENEFIT PACKAGES.—

''(A) IN GENERAL.—Notwithstanding subsection (p), the benefit packages classified as 'H', 'I', and 'J' under the standards established by subsection (p)(2) (including the benefit package classified as 'J' with a high deductible feature, as described in subsection (p)(11)) shall be revised so that—

''(i) the coverage of outpatient prescription drugs available under such benefit packages is replaced with coverage of outpatient prescription drugs that complements but does not duplicate the coverage of outpatient prescription drugs that is otherwise available under this title;

''(ii) the revised benefit packages provide a range of coverage options for outpatient prescription drugs for beneficiaries, but do not provide coverage for more than 90 percent of the cost-sharing amount applicable to an individual under section 1860F(b);

''(iii) uniform language and definitions are used with respect to such revised benefits;

''(iv) uniform format is used in the policy with respect to such revised benefits;

''(v) such revised standards meet any additional requirements imposed by the amendments made by the Medicare Outpatient Prescription Drug Act of 2002; and

''(vi) except as revised under the preceding clauses or as provided under subsection (p)(1)(E), the benefit packages are identical to the benefit packages that were available on the date of enactment of the Medicare Outpatient Prescription Drug Act of 2002.

''(B) MANNER OF REVISION.—The benefit packages revised under this section shall be revised in the manner described in subparagraph (E) of subsection (p)(1), except that for purposes of subparagraph (C) of such subsection, the standards established under this subsection shall take effect not later than January 1, 2005.

''(2) CONSTRUCTION OF BENEFITS IN OTHER MEDICARE SUPPLEMENTAL POLICIES.—Nothing in the benefit packages classified as 'A' through 'G' under the standards established by subsection (p)(2) (including the benefit package classified as 'F' with a high deductible feature, as described in subsection (p)(11)) shall be construed as providing coverage for benefits for which payment may be made under part D.

''(3) GUARANTEED ISSUANCE AND RENEWAL OF REVISED POLICIES.—The provisions of subsections (q) and (s), including provisions of subsection (s)(3) (relating to special enrollment periods in cases of termination or disenrollment), shall apply to medicare supplemental policies revised under this subsection in the same manner as such provisions apply to medicare supplemental policies issued under the standards established under subsection (p).

''(4) OPPORTUNITY OF CURRENT POLICYHOLDERS TO PURCHASE REVISED POLICIES.—

''(A) IN GENERAL.—No medicare supplemental policy of an issuer with a benefit package that is revised under paragraph (1) shall be deemed to meet the standards in subsection (c) unless the issuer—

''(i) provides written notice during the 60-day period immediately preceding the open enrollment period established under section 1860B(a)(3), to each individual who is a policyholder or certificate holder of a medicare supplemental policy issued by that issuer (at the most recent available address of that individual) of the offer described in clause (ii) and of the fact that such individual will no longer be covered under such policy as of January 1, 2005; and

''(ii) offers the policyholder or certificate holder under the terms described in subparagraph (B), during at least the period established under section 1860B(a)(3), a medicare supplemental policy with the benefit package that the Secretary determines is most comparable to the policy in which the individual is enrolled with coverage effective as of the date on which the individual is first entitled to benefits under part D.

''(B) TERMS OF OFFER DESCRIBED.—The terms described in this subparagraph are terms which do not—

''(i) deny or condition the issuance or effectiveness of a medicare supplemental policy described in subparagraph (A)(ii) that is offered and is available for issuance to new enrollees by such issuer;

''(ii) discriminate in the pricing of such policy because of health status, claims experience, receipt of health care, or medical condition; or

''(iii) impose an exclusion of benefits based on a preexisting condition under such policy.

''(5) ELIMINATION OF OBSOLETE POLICIES WITH NO GRANDFATHERING.—No person may sell, issue, or renew a medicare supplemental policy with a benefit package that is classified as 'H', 'I', or 'J' (or with a benefit package classified as 'J' with a high deductible feature) that has not been revised under this subsection on or after January 1, 2005.

''(6) PENALTIES.—Each penalty under this section shall apply with respect to policies revised under this subsection as if such policies were issued under the standards established under subsection (p), including the penalties under subsections (a), (d), (p)(8), (p)(9), (q)(5), (r)(6)(A), (s)(4), and (t)(2)(D).''.

SEC. 206. COMPREHENSIVE IMMUNOSUPPRESSIVE DRUG COVERAGE FOR TRANSPLANT PATIENTS UNDER PART B.

(a) IN GENERAL.—Section 1861(s)(2)(J) of the Social Security Act (42 U.S.C. 1395x(s)(2)(J)), as amended by section 113(a) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (114 Stat. 2763A–473), as enacted into law by section 1(a)(6) of Public Law 106–554, is amended by striking '', to an individual who receives'' and all that follows before the semicolon at the end and inserting ''to an individual who has received an organ transplant''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to drugs furnished on or after the date of enactment of this Act.

SEC. 207. HHS STUDY AND REPORT ON UNIFORM PHARMACY BENEFIT CARDS.

(a) STUDIES.—The Secretary of Health and Human Services shall conduct a study to determine the feasibility and advisability of establishing a uniform format for pharmacy benefit cards provided to beneficiaries by eligible entities under the outpatient prescription drug benefit program under part D of title XVIII of the Social Security Act (as added by section 202).

(b) REPORT.—Not later than 2 years after the date of enactment of this Act, the Secretary of Health and Human Services shall submit to Congress a report on the results of the study conducted under subsection (a) together with any recommendations for legislation that the Secretary determines to be appropriate as a result of such study.

SEC. 208. GAO STUDY AND BIENNIAL REPORTS ON COMPETITION AND SAVINGS.

(a) ONGOING STUDY.—The Comptroller General of the United States shall conduct an ongoing study and analysis of the outpatient prescription drug benefit program under part D of title XVIII of the Social Security Act (as added by section 202), including an analysis of—

(1) the extent to which the competitive bidding process under such program fosters maximum competition and efficiency; and

(2) the savings to the medicare program resulting from such outpatient prescription drug benefit program, including the reduction in the number or length of hospital visits.

(b) INITIAL REPORT ON COMPETITIVE BIDDING PROCESS.—Not later than 9 months after the date of enactment of this Act, the Comptroller General of the United States shall submit to Congress a report on the results of the portion of the study conducted pursuant to subsection (a)(1).

(c) BIENNIAL REPORTS.—Not later than January 1, 2006, and biennially thereafter, the Comptroller General of the United States shall submit to Congress a report on the results of the study conducted under subsection (a) together with such recommendations for legislation and administrative action as the Comptroller General determines appropriate.

SEC. 209. EXPANSION OF MEMBERSHIP AND DUTIES OF MEDICARE PAYMENT ADVISORY COMMISSION (MEDPAC).

(a) EXPANSION OF MEMBERSHIP.—

(1) IN GENERAL.—Section 1805(c) of the Social Security Act (42 U.S.C. 1395b–6(c)) is amended—

(A) in paragraph (1), by striking ''17'' and inserting ''19''; and

(B) in paragraph (2)(B), by inserting ''experts in the area of pharmacology and prescription drug benefit programs,'' after ''other health professionals,''.

(2) INITIAL TERMS OF ADDITIONAL MEMBERS.—

(A) IN GENERAL.—For purposes of staggering the initial terms of members of the Medicare Payment Advisory Commission under section 1805(c)(3) of the Social Security Act (42 U.S.C. 1395b–6(c)(3)), the initial terms of the 2 additional members of the Commission provided for by the amendment under paragraph (1)(A) are as follows:

(i) One member shall be appointed for 1 year.

(ii) One member shall be appointed for 2 years.

(B) COMMENCEMENT OF TERMS.—Such terms shall begin on January 1, 2004.

(b) EXPANSION OF DUTIES.—Section 1805(b)(2) of the Social Security Act (42 U.S.C. 1395b–6(b)(2)) is amended by adding at the end the following new subparagraph:

''(D) PRESCRIPTION MEDICINE BENEFIT PROGRAM.—Specifically, the Commission shall review, with respect to the outpatient prescription drug benefit program under part D, the impact of such program on—

''(i) the pharmaceutical market, including costs and pricing of pharmaceuticals, beneficiary access to such pharmaceuticals, and trends in research and development;

''(ii) franchise, independent, and rural pharmacies; and

''(iii) beneficiary access to outpatient prescription drugs, including an assessment of out-of-pocket spending, generic and brand name drug utilization, and pharmacists' services.''.

SA 4346. Ms. LANDRIEU submitted an amendment intended to be proposed by her to the bill H.R. 5010, making appropriations for the Department of Defense for the fiscal year ending September 30, 2003, and for other purposes; which was ordered to lie on the table; as follows:

On page 223, between lines 20 and 21, insert the following:

SEC. 8124. Of the amount appropriated by title II under the heading ''OPERATION AND MAINTENANCE, NAVY'', up to $4,000,000 may be available for Configuration Management Information Systems.

SA 4347. Ms. LANDRIEU submitted an amendment intended to be proposed by her to the bill H.R. 5010, making appropriations for the Department of Defense for the fiscal year ending September 30, 2003, and for other purposes; which was ordered to lie on the table; as follows:

On page 223, between lines 20 and 21, insert the following:

SEC. 8124. Of the amount appropriated by title II under the heading ''OPERATION AND MAINTENANCE, ARMY'', up to $5,000,000 may be available for the Field Pack-up Containerized Storage Unit.

SA 4348. Ms. LANDRIEU submitted an amendment intended to be proposed by her to the bill H.R. 5010, making appropriations for the Department of Defense for the fiscal year ending September 30, 2003, and for other purposes; which was ordered to lie on the table; as follows:

On page 223, between lines 20 and 21, insert the following:

SEC. 8124. The Secretary of Defense may, using amounts appropriated or otherwise made available by this Act, make a grant to the National D–Day Museum in the amount of $5,000,000.

SA 4349. Mr. HUTCHINSON submitted an amendment intended to be proposed to amendment SA 4345 proposed by Mr. GRAHAM (for himself, Mr. SMITH of Oregon, Mr. MILLER, Mrs. LINCOLN, Mr. BINGAMAN, Mr. KENNEDY, and Ms. STABENOW) to the amendment SA 4299 proposed by Mr. REID (for Mr. DORGAN (for himself, Mr. WELLSTONE, Mr. JEFFORDS, Ms. STABENOW, Ms. COLLINS, Mr. LEVIN, Mr. JOHNSON, Mr. MILLER, Mr. DURBIN, Mr. FEINGOLD, and Mr. HARKIN) to the bill (S. 812) to amend the Federal Food, Drug, and Cosmetic Act to provide greater access to affordable pharmaceuticals; which was ordered to lie on the table; as follows:

On Page 21, strike lines 6 through 20.
On Page 24, strike lines 14 through 22.
On Page 26, strike lines 18 through 25.

On Page 27, strike lines 1 through 3.
On Page 57, strike lines 1 through 25.
On Page 58, strike lines 1 through 22.

AUTHORITY FOR COMMITTEES TO MEET

COMMITTEE ON BANKING, HOUSING, AND URBAN AFFAIRS

Mr. REID. Mr. President, I ask unanimous consent that the Committee on Banking, Housing, and Urban Affairs be authorized to meet during the session of the Senate on Tuesday, July 30, 2002, at 2 p.m. to conduct a hearing on the nominations of Mr. Ben S. Bernanke, of New Jersey, to be a member of the Board of Governors of the Federal Reserve System; and Mr. Donald L. Kohn, of Virginia, to be a member of the Board of Governors of the Federal Reserve System.

The PRESIDING OFFICER. Without objection, it is so ordered.

COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION

Mr. REID. Mr. President, I ask unanimous consent that the Committee on Commerce, Science, and Transportation be authorized to meet on Tuesday, July 30, 2002, at 9:30 a.m. on the Financial Turmoil in the Telecommunications Marketplace; Maintaining the Operations of Essential Communications Facilities.

The PRESIDING OFFICER. Without objection, it is so ordered.

COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS

Mr. REID. Mr. President, I ask unanimous consent that the Committee on Environment and Public Works be authorized to meet on Tuesday, July 30, 2002, at 9:30 a.m. to conduct a hearing to examine the effectiveness of the current Congestion Mitigation and Air Quality, CMAQ, program, conformity, and the role of new technologies.

The hearing will be held in SD–406.

The PRESIDING OFFICER. Without objection, it is so ordered.

COMMITTEE ON FINANCE

Mr. REID. Mr. President, I ask unanimous consent that the Committee on Finance be authorized to meet during the session of the Senate on Tuesday, July 30, 2002, at 10 a.m. to hear testimony on the Role of the Extraterritorial Income Exclusion Act in the International Competitiveness of U.S. Companies.

The PRESIDING OFFICER. Without objection, it is so ordered.

COMMITTEE ON FOREIGN RELATIONS

Mr. REID. Mr. President, I ask unanimous consent that the Committee on Foreign Relations be authorized to meet during the session of the Senate on Tuesday, July 30, 2002, at 9 a.m. to hold a business meeting.

Agenda

The Committee will consider and vote on the following agenda items:

Treaties

1. Treaty Doc. 96–53; Convention on the Elimination of All Forms of Discrimination Against Women, adopted by the U.N. General Assembly on December 18, 1979, and signed on behalf of the United States of America on July 17, 1980.

2. Treaty Doc. 103–5; Protocol Concerning Specially Protected Areas and Wildlife to the Convention for the Protection and Development of the Marine Environment of the Wider Caribbean Region, done at Kingston on January 18, 1990.

2. Treaty Doc. 107–2; Protocol to Amend the 1949 Convention on the Establishment of an Inter-American Tropical Tuna Commission, done at Guayaquil, June 11, 1999, and signed by the United States, subject to ratification, in Guayaquil, Ecuador, on the same date.

Legislation

1. S. 1777, A bill to authorize assistance for individuals with disabilities in foreign countries, including victims of landmines and other victims of civil strife and warfare, and for other purposes, with amendments.

Nominations

1. Mr. John Blaney, of Virginia, to be Ambassador to the Republic of Liberia.

2. Ms. Aurelia Brazeal, of Georgia, to be Ambassador to the Federal Democratic Republic of Ethiopia.

3. Mr. Martin Brennan, of California, to be Ambassador to the Republic of Zambia.

4. Mr. J. Anthony Holmes, of California, to be Ambassador to Burkina Faso.

5. Ms. Vicki Huddleston, of Arizona, to be Ambassador to the Republic of Mali.

6. Mr. Donald Johnson, of Texas, to be Ambassador to the Republic of Cape Verde.

7. Ms. Kristie A. Kenney, of Maryland, to be Ambassador to the Republic of Ecuador.

8. Mr. Jimmy Kolker, of Missouri, to be Ambassador to the Republic of Uganda.

9. Ms. Gail Mathieu, of New Jersey, to be Ambassador to the Republic of Niger.

10. Mrs. Barbara C. Moore, of Maryland, to be Ambassador to the Republic of Nicaragua.

11. Mr. Larry L. Palmer, of Georgia, to be Ambassador to the Republic of Honduras.

12. Mr. James Yellin, of Pennsylvania, to be Ambassador to the Republic of Burundi.

Additional items may be announced.

The PRESIDING OFFICER. Without objection, it is so ordered.

COMMITTEE ON FOREIGN RELATIONS

Mr. REID. Mr. President, I ask unanimous consent that the Committee on Foreign Relations be authorized to meet during the session of the Senate on Tuesday, July 30, 2002, at 11 a.m. to hold a nomination hearing.

Agenda

Nominees

Ms. Nancy J. Powell, of Iowa, to be Ambassador to the Islamic Republic of Pakistan.

Mr. Richard L. Baltimore, III, of New York, to be Ambassador to the Sultanate of Oman.

The PRESIDING OFFICER. Without objection, it is so ordered.

COMMITTEE ON INDIAN AFFAIRS

Mr. REID. Mr. President, I ask unanimous consent that the Committee on Indian Affairs be authorized to meet on Tuesday, July 30, 2002, at 10:00 a.m. in Room 106 of the Dirksen Senate Office Building to conduct a hearing on a Legislative Proposal of the Department of Interior/Tribal Trust Fund Reform Task Force; to be followed immediately by a second hearing on S. 2212, a bill to establish a direct line of authority for the Office of Trust Reform Implementations and Oversight to oversee the management and reform of Indian trust funds and assets under the jurisdiction of the Department of the Interior, and to advance tribal management of such funds and assets, pursuant to the Indian Self-Determinations Act and for other purposes.

The PRESIDING OFFICER. Without objection, it is so ordered.

SUBCOMMITTEE ON CONSUMER AFFAIRS

Mr. REID. Mr. President, I ask unanimous consent that the subcommittee on Consumer Affairs of the Committee on Commerce, Science, and Transportation be authorized to meet on Tuesday, July 30, 2002, at 2:30 pm on improving consumer choice in auto repair shops.

The PRESIDING OFFICER. Without objection, it is so ordered.

SUBCOMMITTEE ON EMERGING THREATS AND CAPABILITIES

Mr. REID. Mr. President, I ask unanimous consent that the Subcommittee on Emerging Threats and Capabilities of the Committee on Armed Services be authorized to meet during the session of the Senate on Tuesday, July 30, 2002, at 2:30 p.m., in open session to receive testimony on the report of the General Accounting Office on Nuclear Nonproliferation and efforts to help other countries combat nuclear smuggling.

The PRESIDING OFFICER. Without objection, it is so ordered.

SUBCOMMITTEE ON PUBLIC LANDS AND FORESTS

Mr. REID. Mr. President, I ask unanimous consent that the Subcommittee on Public Lands and Forests of the Committee on Energy and Natural Resources be authorized to hold a Hearing during the session of the Senate on Tuesday, July 30, 2002, at 2:30 p.m. in SD–366. The purpose of this hearing is to receive testimony on the following bills:

S. 2016, to authorize an exchange of lands between an Alaska Native Village Corporation and the Department of the Interior, and for other purposes;

S. 2565, to enhance ecosystem protection and the range of outdoor opportunities protected by statute in the